

## Human Tissue Bill

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### EXPLANATORY NOTES

Explanatory notes to the Bill, prepared by the Department of Health, are published separately as EN—9.

### EUROPEAN CONVENTION ON HUMAN RIGHTS

Mr Secretary Reid has made the following statement under section 19(1)(a) of the Human Rights Act 1998:

In my view the provisions of the Human Tissue Bill are compatible with the Convention rights.

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AMERICAN MEDICAL ASSOCIATION

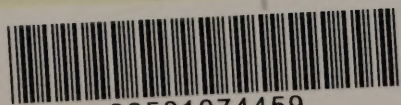
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# Human Tissue Bill

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## CONTENTS

### PART 1

#### REMOVAL, STORAGE AND USE OF HUMAN ORGANS AND OTHER TISSUE FOR SCHEDULED PURPOSES

- 1 Authorisation of activities for scheduled purposes
- 2 “Appropriate consent”: children
- 3 “Appropriate consent”: adults
- 4 Nominated representatives
- 5 Prohibition of activities without consent etc.
- 6 Restriction of activities in relation to donated material
- 7 Existing holdings
- 8 Existing anatomical specimens
- 9 Coroners

### PART 2

#### REGULATION OF ACTIVITIES INVOLVING HUMAN TISSUE

##### *The Human Tissue Authority*

- 10 The Human Tissue Authority
- 11 Remit
- 12 General functions

##### *Licensing*

- 13 Licence requirement
- 14 Persons to whom licence applies
- 15 Duty of the designated individual
- 16 Right to reconsideration of licensing decisions
- 17 Appeals committees
- 18 Procedure on reconsideration
- 19 Appeal on point of law
- 20 Conduct of licensed activities
- 21 Changes of licence circumstance
- 22 Breach of licence requirement

### *Codes of practice*

- 23 Preparation of codes
- 24 Provision with respect to consent
- 25 Effect of codes
- 26 Approval of codes

### *Anatomy*

- 27 Possession of anatomical specimens away from licensed premises
- 28 Possession of former anatomical specimens away from licensed premises

### *Trafficking*

- 29 Prohibition of commercial dealings in human material

### *Transplants*

- 30 Restriction on transplants involving a live donor
- 31 Information about transplant operations

### *Inspectorates*

- 32 Inspectorate of Anatomy and Pathology
- 33 Remit of Inspectorate of Anatomy and Pathology
- 34 Inspectorate of Organ and Tissue for Human Use
- 35 Remit of Inspectorate of Organ and Tissue for Human Use
- 36 Duties in relation to discharge of functions by Inspectorates

### *General*

- 37 Agency arrangements and provision of services
- 38 Annual report
- 39 Directions

### *Exceptions*

- 40 Criminal justice purposes
- 41 Religious relics

### *Supplementary*

- 42 "Qualifying museum"
- 43 Interpretation of Part 2

## **PART 3**

### **MISCELLANEOUS AND GENERAL**

#### *Miscellaneous*

- 44 Preservation for transplantation
- 45 Surplus tissue
- 46 Offences relating to non-consensual analysis of DNA
- 47 Purposes for which DNA may be analysed without consent



- 48 Power to give effect to Community obligations
- 49 Power to de-accession human remains

### *General*

- 50 Powers of inspection, entry, search and seizure
- 51 Offences by bodies corporate
- 52 Prosecutions
- 53 Offences: Northern Ireland and Scotland
- 54 Orders and regulations
- 55 "Relevant material"
- 56 General interpretation
- 57 Financial provisions
- 58 Consequential amendments
- 59 Repeals and revocations
- 60 Transition
- 61 Extent
- 62 Commencement
- 63 Short title

- 
- Schedule 1 – Scheduled purposes
    - Part 1 – Purposes normally requiring consent
    - Part 2 – Purposes not normally requiring consent
  - Schedule 2 – The Human Tissue Authority
  - Schedule 3 – Licences for the purposes of section 13
  - Schedule 4 – Inspectorates: Boards
  - Schedule 5 – Section 46: Qualifying consent
    - Part 1 – England and Wales and Northern Ireland
    - Part 2 – Scotland
  - Schedule 6 – Powers of inspection, entry, search and seizure
  - Schedule 7 – Consequential amendments
  - Schedule 8 – Repeals and revocations
    - Part 1 – Repeals
    - Part 2 – Revocations





# A B I L L

TO

Make provision with respect to activities involving human tissue; to make provision about the transfer of human remains from certain museum collections; and for connected purposes.

**B**E IT ENACTED by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

## PART 1

### REMOVAL, STORAGE AND USE OF HUMAN ORGANS AND OTHER TISSUE FOR SCHEDULED PURPOSES

#### 1 Authorisation of activities for scheduled purposes

- (1) The following activities shall be lawful if done with appropriate consent—
  - (a) the storage of the body of a deceased person for use for a purpose specified in Schedule 1, other than anatomical examination; 5
  - (b) the use of the body of a deceased person for a purpose so specified, other than anatomical examination;
  - (c) the removal from the body of a deceased person, for use for a purpose specified in Schedule 1, of any relevant material of which the body consists or which it contains; 10
  - (d) the storage for use for a purpose specified in Part 1 of Schedule 1 of any relevant material which has come from a human body;
  - (e) the storage for use for a purpose specified in Part 2 of Schedule 1 of any relevant material which has come from the body of a deceased person; 15
  - (f) the use for a purpose specified in Part 1 of Schedule 1 of any relevant material which has come from a human body;
  - (g) the use for a purpose specified in Part 2 of Schedule 1 of any relevant material which has come from the body of a deceased person. 20
- (2) The storage of the body of a deceased person for use for the purpose of anatomical examination shall be lawful if done—
  - (a) with appropriate consent, and



- (b) after the signing of a certificate –
    - (i) under section 22(1) of the Births and Deaths Registration Act 1953 (c. 20), or
    - (ii) under Article 25(2) of the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I. 14)),  
of the cause of death of the person. 5
- (3) The use of the body of a deceased person for the purpose of anatomical examination shall be lawful if done –
  - (a) with appropriate consent, and
  - (b) after the death of the person has been registered – 10
    - (i) under section 15 of the Births and Deaths Registration Act 1953, or
    - (ii) under Article 21 of the Births and Deaths Registration (Northern Ireland) Order 1976.
- (4) Subsections (1) to (3) do not apply to an activity of a kind mentioned there if it is done in relation to – 15
  - (a) a body to which subsection (5) applies, or
  - (b) relevant material to which subsection (6) applies.
- (5) This subsection applies to a body if – 20
  - (a) it has been imported, or
  - (b) it is the body of a person who died before the day on which this section comes into force and at least one hundred years have elapsed since the date of the person's death.
- (6) This subsection applies to relevant material if – 25
  - (a) it has been imported,
  - (b) it has come from a body which has been imported, or
  - (c) it is material which has come from the body of a person who died before the day on which this section comes into force and at least one hundred years have elapsed since the date of the person's death.
- (7) The following activities shall be lawful – 30
  - (a) the storage for use for a purpose specified in Part 2 of Schedule 1 of any relevant material which has come from the body of a living person;
  - (b) the use for such a purpose of any relevant material which has come from the body of a living person;
  - (c) an activity in relation to which subsection (4) has effect. 35
- (8) The Secretary of State may by order –
  - (a) vary or omit any of the purposes specified in Part 1 or 2 of Schedule 1, or
  - (b) add to the purposes specified in Part 1 or 2 of that Schedule.
- (9) In this section, the references to a body or material which has been imported do not include a body or material which has been imported after having been exported with a view to its subsequently being re-imported. 40



## 2 “Appropriate consent”: children

- (1) This section makes provision for the interpretation of “appropriate consent” in section 1 in relation to an activity involving the body, or material from the body, of a person who is a child or has died a child (“the child concerned”).
- (2) Subject to subsection (3), where the child concerned is alive, “appropriate consent” means his consent. 5
- (3) Where—
  - (a) the child concerned is alive,
  - (b) neither a decision of his to consent to the activity, nor a decision of his not to consent to it, is in force, and 10
  - (c) either he is not competent to deal with the issue of consent in relation to the activity or, though he is competent to deal with that issue, he fails to do so,“appropriate consent” means the consent of a person who has parental responsibility for him. 15
- (4) Where the child concerned has died and the activity involves storage for use, or use, for the purpose of anatomical examination or public display, “appropriate consent” means his consent in writing.
- (5) Consent in writing for the purposes of subsection (4) is only valid if—
  - (a) it is signed by the child concerned in the presence of at least one witness who attests the signature, or 20
  - (b) it is signed at the direction of the child concerned, in his presence and in the presence of at least one witness who attests the signature.
- (6) Where the child concerned has died and the activity does not involve storage for use, or use, for the purpose of anatomical examination or public display, “appropriate consent” means — 25
  - (a) if a decision of his to consent to the activity, or a decision of his not to consent to it, was in force immediately before he died, his consent;
  - (b) if paragraph (a) does not apply—
    - (i) the consent of a person who had parental responsibility for him immediately before he died, or 30
    - (ii) where no person had parental responsibility for him immediately before he died, the consent of a person who stood in a qualifying relationship to him at that time.

## 3 “Appropriate consent”: adults 35

- (1) This section makes provision for the interpretation of “appropriate consent” in section 1 in relation to an activity involving the body, or material from the body, of a person who is an adult or has died an adult (“the person concerned”).
- (2) Where the person concerned is alive, “appropriate consent” means his consent. 40
- (3) Where the person concerned has died and the activity involves storage for use, or use, for the purpose of anatomical examination or public display, “appropriate consent” means his consent in writing.
- (4) Consent in writing for the purposes of subsection (3) is only valid if—



- (a) it is signed by the person concerned in the presence of at least one witness who attests the signature,
  - (b) it is signed at the direction of the person concerned, in his presence and in the presence of at least one witness who attests the signature, or
  - (c) it is contained in a will of the person concerned made in accordance with the requirements of –
    - (i) section 9 of the Wills Act 1837 (c. 26), or
    - (ii) Article 5 of the Wills and Administration Proceedings (Northern Ireland) Order 1994 (S.I. 1994/1899 (N.I. 13)).
- (5) Where the person concerned has died and the activity does not involve storage for use, or use, for the purpose of anatomical examination or public display, “appropriate consent” means –
  - (a) if a decision of his to consent to the activity, or a decision of his not to consent to it, was in force immediately before he died, his consent;
  - (b) if –
    - (i) paragraph (a) does not apply, and
    - (ii) he has appointed a person or persons under section 4 to deal after his death with the issue of consent in relation to the activity,
 consent given under the appointment;
  - (c) if neither paragraph (a) nor paragraph (b) applies, the consent of a person who stood in a qualifying relationship to him immediately before he died.
- (6) Where the person concerned has appointed a person or persons under section 4 to deal after his death with the issue of consent in relation to the activity, the appointment shall be disregarded for the purposes of subsection (5) if no one is able to give consent under it.
- (7) If it is not reasonably practicable to communicate with a person appointed under section 4 within the time available if consent in relation to the activity is to be acted on, he shall be treated for the purposes of subsection (6) as not able to give consent under the appointment in relation to it.

#### 4 Nominated representatives

- (1) An adult may appoint one or more persons to represent him after his death in relation to consent for the purposes of section 1.
- (2) An appointment under this section may be general or limited to consent in relation to such one or more activities as may be specified in the appointment.
- (3) An appointment under this section may be made orally or in writing.
- (4) An oral appointment under this section is only valid if made in the presence of at least two witnesses present at the same time.
- (5) A written appointment under this section is only valid if –
  - (a) it is signed by the person making it in the presence of at least one witness who attests the signature,
  - (b) it is signed at the direction of the person making it, in his presence and in the presence of at least one witness who attests the signature, or
  - (c) it is contained in a will of the person making it, being a will which is made in accordance with the requirements of –



- (i) section 9 of the Wills Act 1837 (c. 26), or
  - (ii) Article 5 of the Wills and Administration Proceedings (Northern Ireland) Order 1994 (S.I. 1994/1899 (N.I. 13)).
- (6) Where a person appoints two or more persons under this section in relation to the same activity, they shall be regarded as appointed to act jointly and severally unless the appointment provides that they are appointed to act jointly. 5
- (7) An appointment under this section may be revoked at any time.
- (8) Subsections (3) to (5) apply to the revocation of an appointment under this section as they apply to the making of such an appointment. 10
- (9) A person appointed under this section may at any time renounce his appointment.
- (10) A person may not act under an appointment under this section if—
  - (a) he is not an adult, or
  - (b) he is of a description prescribed for the purposes of this provision by regulations made by the Secretary of State. 15

## 5 Prohibition of activities without consent etc.

- (1) A person commits an offence if, without appropriate consent, he does an activity to which subsection (1), (2) or (3) of section 1 applies, unless he reasonably believes— 20
  - (a) that he does the activity with appropriate consent, or
  - (b) that what he does is not an activity to which the subsection applies.
- (2) Subject to subsection (3), a person commits an offence if, when he does an activity to which section 1(2) applies, neither of the following has been signed in relation to the cause of death of the person concerned— 25
  - (a) a certificate under section 22(1) of the Births and Deaths Registration Act 1953 (c. 20), and
  - (b) a certificate under Article 25(2) of the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I. 14)).
- (3) Subsection (2) does not apply— 30
  - (a) where the person reasonably believes—
    - (i) that a certificate under either of those provisions has been signed in relation to the cause of death of the person concerned, or
    - (ii) that what he does is not an activity to which section 1(2) applies, or 35
  - (b) where the person comes into lawful possession of the body immediately after death and stores it prior to its removal to a place where anatomical examination is to take place.
- (4) Subject to subsection (5), a person commits an offence if, when he does an activity to which section 1(3) applies, the death of the person concerned has not been registered under either of the following provisions— 40
  - (a) section 15 of the Births and Deaths Registration Act 1953, and
  - (b) Article 21 of the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I. 14)). 45

- (5) Subsection (4) does not apply where the person reasonably believes –
    - (a) that the death of the person concerned has been registered under either of those provisions, or
    - (b) that what he does is not an activity to which section 1(3) applies.
  - (6) A person guilty of an offence under this section shall be liable – 5
    - (a) on summary conviction –
      - (i) to imprisonment for a term not exceeding 12 months, or
      - (ii) to a fine not exceeding the statutory maximum, or
      - (iii) to both;
    - (b) on conviction on indictment – 10
      - (i) to imprisonment for a term not exceeding 3 years, or
      - (ii) to a fine, or
      - (iii) to both.
  - (7) In this section, “appropriate consent” has the same meaning as in section 1.
- 6      Restriction of activities in relation to donated material** 15
- (1) Subject to subsection (2), a person commits an offence if he –
    - (a) uses donated material for a purpose which is not a qualifying purpose, or
    - (b) stores donated material for use for a purpose which is not a qualifying purpose. 20
  - (2) Subsection (1) does not apply where the person reasonably believes that what he uses, or stores, is not donated material.
  - (3) A person guilty of an offence under this section shall be liable –
    - (a) on summary conviction –
      - (i) to imprisonment for a term not exceeding 12 months, or 25
      - (ii) to a fine not exceeding the statutory maximum, or
      - (iii) to both;
    - (b) on conviction on indictment –
      - (i) to imprisonment for a term not exceeding 3 years, or
      - (ii) to a fine, or 30
      - (iii) to both.
  - (4) In subsection (1), references to a qualifying purpose are to –
    - (a) a purpose specified in Schedule 1,
    - (b) the purpose of medical diagnosis or treatment,
    - (c) the purpose of decent disposal, or 35
    - (d) a purpose specified in regulations made by the Secretary of State.
  - (5) In this section, references to donated material are to –
    - (a) the body of a deceased person, or
    - (b) relevant material which has come from a human body, 40
 which is, or has been, the subject of donation.
  - (6) For the purposes of subsection (5), a body, or material, is the subject of donation if authority under section 1(1) to (3) exists in relation to it.



## 7 Existing holdings

- (1) In its application to the following activities, section 1(1) shall have effect with the omission of the words “if done with appropriate consent” –
  - (a) the storage of an existing holding for use for a purpose specified in Schedule 1, other than anatomical examination; 5
  - (b) the use of an existing holding for a purpose so specified, other than anatomical examination.
- (2) In this section, “existing holding” means –
  - (a) the body of a deceased person, or
  - (b) relevant material which has come from a human body, 10
 held, immediately before the day on which section 1(1) comes into force, for use for a purpose specified in Schedule 1, other than anatomical examination.

## 8 Existing anatomical specimens

- (1) This section applies where a person dies during the three years immediately preceding the coming into force of section 1. 15
- (2) Subsection (3) applies where –
  - (a) before section 1 comes into force, authority is given under section 4(2) or (3) of the Anatomy Act 1984 (c. 14) for the person’s body to be used for anatomical examination, and
  - (b) section 1 comes into force before anatomical examination of the person’s body is concluded. 20
- (3) During so much of the relevant period as falls after section 1 comes into force, that authority shall be treated for the purposes of section 1 as appropriate consent in relation to –
  - (a) the storage of the person’s body, or separated parts of his body, for use for the purpose of anatomical examination, and 25
  - (b) the use of his body, or separated parts of his body, for that purpose.
- (4) Subsection (5) applies where –
  - (a) before section 1 comes into force, authority is given under section 6(2) or (3) of the Anatomy Act 1984 for possession of parts (or any specified parts) of the person’s body to be held after anatomical examination of his body is concluded, and 30
  - (b) anatomical examination of the person’s body is concluded –
    - (i) after section 1 comes into force, but
    - (ii) before the end of the period of three years beginning with the date of the person’s death. 35
- (5) With effect from the conclusion of the anatomical examination of the person’s body, that authority shall be treated for the purposes of section 1 as appropriate consent in relation to –
  - (a) the storage for use for a qualifying purpose of a part of the person’s body which – 40
    - (i) is a part to which that authority relates, and
    - (ii) is such that the person cannot be recognised simply by examination of the part, and
  - (b) the use for a qualifying purpose of such a part of the person’s body. 45

- (6) Where for the purposes of section 1 there would not be appropriate consent in relation to an activity but for authority given under the Anatomy Act 1984 (c. 14) being treated for those purposes as appropriate consent in relation to the activity, section 1(1) to (3) do not authorise the doing of the activity otherwise than in accordance with that authority. 5
- (7) In subsection (3), “the relevant period”, in relation to a person, means whichever is the shorter of—
- (a) the period of three years beginning with the date of the person’s death, and
  - (b) the period beginning with that date and ending when anatomical examination of the person’s body is concluded. 10
- (8) In subsection (5), “qualifying purpose” means a purpose specified in paragraph 3 or 7 of Schedule 1.
- (9) The Secretary of State may by order amend subsection (8).
- 9 Coroners** 15
- (1) Nothing in this Part applies to anything done for purposes of functions of a coroner or under the authority of a coroner.
- (2) Where a person knows, or has reason to believe, that—
- (a) the body of a deceased person, or
  - (b) relevant material which has come from the body of a deceased person, 20
- is, or may be, required for purposes of functions of a coroner, he shall not act on authority under section 1 in relation to the body, or material, except with the consent of the coroner.

## PART 2

### REGULATION OF ACTIVITIES INVOLVING HUMAN TISSUE 25

#### *The Human Tissue Authority*

- 10 The Human Tissue Authority**
- (1) There shall be a body corporate to be known as the Human Tissue Authority (referred to in this Act as “the Authority”).
- (2) Schedule 2 (which makes further provision about the Authority) has effect. 30
- 11 Remit**
- (1) The following are the activities within the remit of the Authority—
- (a) the removal from a human body, for use for a scheduled purpose, of any relevant material of which the body consists or which it contains;
  - (b) the use, for a scheduled purpose, of— 35
    - (i) the body of a deceased person, or
    - (ii) relevant material which has come from a human body;
  - (c) the storage of an anatomical specimen or former anatomical specimen;
  - (d) the storage (in any case not falling within paragraph (c)) of—
    - (i) the body of a deceased person, or 40



- (ii) relevant material which has come from a human body, for use for a scheduled purpose;
  - (e) the import or export of—
    - (i) the body of a deceased person, or
    - (ii) relevant material which has come from a human body, for use for a scheduled purpose; 5
  - (f) the disposal of the body of a deceased person which has been—
    - (i) imported for use,
    - (ii) stored for use, or
    - (iii) used, 10
 for a scheduled purpose;
  - (g) the disposal of relevant material which—
    - (i) has been removed from a person’s body for the purposes of his medical treatment,
    - (ii) has been removed from the body of a deceased person for the purposes of an anatomical, or post-mortem, examination, 15
    - (iii) has been removed from a human body (otherwise than as mentioned in sub-paragraph (ii)) for use for a scheduled purpose,
    - (iv) has come from a human body and been imported for use for a scheduled purpose, or 20
    - (v) has come from the body of a deceased person which has been imported for use for a scheduled purpose.
- (2) Without prejudice to the generality of subsection (1)(a) and (b), the activities within the remit of the Authority include, in particular— 25
  - (a) the carrying-out of an anatomical examination, and
  - (b) the making of a post-mortem examination.
- (3) An activity is excluded from the remit of the Authority if it is done for purposes of a qualifying museum.
- (4) The Secretary of State may by order amend this section for the purpose of adding to the activities within the remit of the Authority. 30
- (5) In this section, “relevant material”, in relation to use for the scheduled purpose of transplantation, does not include blood or anything derived from blood.

## 12 General functions

- The Authority shall have the following general functions— 35
- (a) maintaining a statement of the general principles which it considers should be followed—
    - (i) in the carrying-on of activities within its remit, and
    - (ii) in the carrying-out of its functions in relation to such activities;
  - (b) providing in relation to activities within its remit such general oversight and guidance as it considers appropriate; 40
  - (c) superintending, in relation to activities within its remit, compliance with—
    - (i) requirements imposed by or under Part 1 or this Part, and
    - (ii) codes of practice under this Act; 45

- (d) providing to the public, and to persons carrying on activities within its remit, such information and advice as it considers appropriate about the nature and purpose of such activities;
- (e) monitoring developments relating to activities within its remit and advising the Secretary of State, the National Assembly for Wales and the relevant Northern Ireland department on issues relating to such developments; 5
- (f) advising the Secretary of State, the National Assembly for Wales or the relevant Northern Ireland department on such other issues relating to activities within its remit as he, the Assembly or the department may require. 10

### *Licensing*

## 13 Licence requirement

- (1) No person shall do an activity to which this section applies otherwise than under the authority of a licence granted for the purposes of this section. 15
- (2) This section applies to the following activities –
  - (a) the carrying-out of an anatomical examination;
  - (b) the making of a post-mortem examination;
  - (c) the removal from the body of a deceased person (otherwise than for the purposes of an anatomical, or post-mortem, examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation; 20
  - (d) the storage of an anatomical specimen;
  - (e) the storage (in any case not falling within paragraph (d)) of –
    - (i) the body of a deceased person, or 25
    - (ii) relevant material which has come from a human body, for use for a scheduled purpose;
  - (f) the use, for the purpose of public display, of –
    - (i) the body of a deceased person, or
    - (ii) relevant material which has come from the body of a deceased person. 30
- (3) The Secretary of State may by regulations specify circumstances in which storage of relevant material by a person who intends to use it for a scheduled purpose is excepted from subsection (2)(e)(ii).
- (4) An activity is excluded from subsection (2) if it is done for purposes of a qualifying museum. 35
- (5) The Secretary of State may by regulations amend this section for the purpose of –
  - (a) adding to the activities to which this section applies,
  - (b) removing an activity from the activities to which this section applies, or 40
  - (c) altering the description of an activity to which this section applies.
- (6) Schedule 3 (which makes provision about licences for the purposes of this section) has effect.
- (7) In subsection (2) –



- (a) references to storage do not include storage which is incidental to transportation, and
- (b) “relevant material”, in relation to use for the scheduled purpose of transplantation, does not include blood or anything derived from blood.

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#### 14 Persons to whom licence applies

The authority conferred by a licence extends to—

- (a) the designated individual,
- (b) any person who is designated as a person to whom the licence applies by a notice given to the Authority by the designated individual, and
- (c) any person acting under the direction of—
  - (i) the designated individual, or
  - (ii) a person designated as mentioned in paragraph (b).

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#### 15 Duty of the designated individual

It shall be the duty of the individual designated in a licence as the person under whose supervision the licensed activity is authorised to be carried on to secure—

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- (a) that the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity,
- (b) that suitable practices are used in the course of carrying on that activity, and
- (c) that the conditions of the licence are complied with.

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#### 16 Right to reconsideration of licensing decisions

- (1) If an application for the grant, revocation or variation of a licence is refused, the applicant may require the Authority to reconsider the decision. 25
- (2) If a licence is —
  - (a) revoked under paragraph 7(2) of Schedule 3, or
  - (b) varied under paragraph 8(3) or (5) of that Schedule,the holder of the licence, or the designated individual, may require the Authority to reconsider the decision. 30
- (3) If an application for the grant, or revocation, of permission for the purposes of an authorisation condition is refused, the applicant may require the Authority to reconsider the decision.
- (4) If permission for the purposes of an authorisation condition is revoked under paragraph 12(4)(b) of Schedule 3, any of—
  - (a) the individual concerned,
  - (b) the holder of the licence, and
  - (c) the designated individual,may require the Authority to reconsider the decision. 35
- (5) The right under subsection (1) or (2) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 28 days beginning with the day on which notice of the decision concerned was given under paragraph 11 of Schedule 3. 40

- (6) The right under subsection (3) or (4) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 28 days beginning with the day on which notice of the decision concerned was given under paragraph 12 of Schedule 3.
- (7) Subsections (1) to (4) do not apply to a decision on reconsideration. 5
- (8) In this section, “authorisation condition” means a condition of a licence where—
  - (a) the licence is one to which paragraph 3 of Schedule 3 applies, and
  - (b) the condition is the one required in the licence by sub-paragraph (2) of that paragraph. 10

## 17 Appeals committees

- (1) The Authority shall maintain one or more committees to carry out its functions in pursuance of notices under section 16.
- (2) A committee under subsection (1) is referred to in this Part as an appeals committee. 15
- (3) An appeals committee shall consist of not less than five members of the Authority.
- (4) The quorum for an appeals committee shall be three.

## 18 Procedure on reconsideration

- (1) Reconsideration shall be by way of fresh decision. 20
- (2) On reconsideration—
  - (a) the person by whom reconsideration is required (“the appellant”) shall be entitled to require that he or his representative be given an opportunity to appear before and be heard by the appeals committee dealing with the matter, 25
  - (b) at any meeting at which such an opportunity is given, the person who made the decision which is the subject of reconsideration shall be entitled to appear and be heard in person or by a representative, and
  - (c) the appeals committee dealing with the matter shall consider any written representations received from the appellant or the person who made the decision which is the subject of reconsideration. 30
- (3) The appeals committee by which a decision is reconsidered in pursuance of a notice under section 16 shall give the appellant notice of its decision.
- (4) If on reconsideration an appeals committee upholds the previous decision, the notice under subsection (3) shall include a statement of the reasons for the appeals committee’s decision. 35
- (5) The Authority may by regulations make such other provision about procedure in relation to reconsideration as it thinks fit.
- (6) Where reconsideration of a decision—
  - (a) is required under section 16(2) or (4) by only one of two persons by whom it could have been required, or 40
  - (b) is required under section 16(4) by only one or two of three persons by whom it could have been required,



it shall be treated for the purposes of this section as required by both or (as the case may be) all of them.

- (7) In this section, “reconsideration” means reconsideration in pursuance of a notice under section 16.

## **19 Appeal on point of law**

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A person aggrieved by a decision on reconsideration in pursuance of a notice under section 16 may appeal to the High Court on a point of law.

## **20 Conduct of licensed activities**

- (1) Directions may impose requirements in relation to the conduct of the activity which a licence authorises to be carried on. 10
- (2) Directions under subsection (1) may be given in relation to licences generally, licences of a particular description or a particular licence.
- (3) A person shall comply with a requirement imposed by directions under subsection (1) if it is applicable to him.

## **21 Changes of licence circumstance**

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- (1) Directions may make provision for the purpose of dealing with a situation arising in consequence of –
- (a) the variation of a licence, or
  - (b) a licence ceasing to have effect.
- (2) Directions under subsection (1)(a) may impose requirements – 20
- (a) on the holder of the licence;
  - (b) on a person who is the designated individual immediately before, or immediately after, the variation;
  - (c) on any other person, if he consents.
- (3) Directions under subsection (1)(b) may impose requirements – 25
- (a) on the person who is the holder of the licence immediately before the licence ceases to have effect;
  - (b) on the person who is the designated individual at that time;
  - (c) on any other person, if he consents.
- (4) Directions under subsection (1) may, in particular, require anything kept, or information held, in pursuance of the licence to be transferred in accordance with the directions. 30
- (5) Where a licence has ceased to have effect by reason of the death or dissolution of its holder, anything subsequently done by a person before directions are given under subsection (1) shall, if the licence would have been authority for doing it, be treated as authorised by a licence. 35

## **22 Breach of licence requirement**

- (1) A person who contravenes section 13(1) commits an offence, unless he reasonably believes –
- (a) that what he does is not an activity to which section 13 applies, or 40

- (b) that he acts under the authority of a licence.
- (2) A person guilty of an offence under subsection (1) shall be liable –
  - (a) on summary conviction –
    - (i) to imprisonment for a term not exceeding 12 months, or
    - (ii) to a fine not exceeding the statutory maximum, or
    - (iii) to both; 5
  - (b) on conviction on indictment –
    - (i) to imprisonment for a term not exceeding 3 years, or
    - (ii) to a fine, or
    - (iii) to both. 10

*Codes of practice*

### 23 Preparation of codes

- (1) The Authority may prepare codes of practice for the purpose of –
  - (a) giving practical guidance to persons carrying on activities within its remit, and 15
  - (b) laying down the standards expected in relation to the carrying-on of such activities.
- (2) The Authority shall deal under subsection (1) with the following matters –
  - (a) the conduct of anatomical examinations;
  - (b) the storage of anatomical specimens; 20
  - (c) the storage and disposal of former anatomical specimens;
  - (d) the definition of death for the purposes of this Act;
  - (e) communication with the family of the deceased in relation to the making of a post-mortem examination;
  - (f) the conduct of post-mortem examinations; 25
  - (g) communication with the family of the deceased in relation to the removal from the body of the deceased, for use for a scheduled purpose, of any relevant material of which the body consists or which it contains;
  - (h) the removal from a human body, for use for a scheduled purpose, of any relevant material of which the body consists or which it contains; 30
  - (i) the storage for use for a scheduled purpose, and the use for such a purpose, of relevant material which has come from a human body;
  - (j) the storage for use for a scheduled purpose, and the use for such a purpose, of an existing holding within the meaning of section 7; 35
  - (k) the import, and the export, of –
    - (i) the body of a deceased person, or
    - (ii) relevant material which has come from a human body, for use for a scheduled purpose;
  - (l) the disposal of relevant material which – 40
    - (i) has been removed from a human body for use for a scheduled purpose, or
    - (ii) has come from a human body and is an existing holding for the purposes of section 7.
- (3) The Authority shall – 45



- (a) keep any code of practice under this section under review, and
  - (b) prepare a revised code of practice when appropriate.
- (4) Before preparing a code of practice under this section, the Authority shall—
  - (a) consult such persons as it considers appropriate,
  - (b) if the code of practice relates to Wales, consult the National Assembly for Wales, and
  - (c) if the code of practice relates to Northern Ireland, consult the relevant Northern Ireland department.
- (5) The Authority shall publish a code of practice under this section in such way as, in its opinion, is likely to bring it to the attention of those interested.
- (6) Codes of practice under this section may make different provision in relation to England, Wales and Northern Ireland respectively.

## 24 Provision with respect to consent

- (1) In dealing under section 23(1) with the matters mentioned in—
  - (a) section 23(2)(e) and (g), and
  - (b) so far as relating to the body of a deceased person, section 23(2)(h),
 the Authority shall, in particular, lay down the standards expected in relation to the obtaining of consent for the purposes of section 1.
- (2) Subject to subsection (3), the standards required to be laid down by subsection (1) shall include provision to the effect set out in subsections (4) to (8).
- (3) The standards required to be laid down by subsection (1) may include provision to different effect in relation to cases which appear to the Authority to be exceptional.
- (4) The qualifying relationships for the purpose of sections 2(6)(b)(ii) and 3(5)(c) should be ranked in the following order—
  - (a) spouse or partner;
  - (b) parent or child;
  - (c) brother or sister;
  - (d) child of a person falling within paragraph (c);
  - (e) stepfather or stepmother;
  - (f) half-brother or half-sister;
  - (g) friend of longstanding.
- (5) Relationships in the same paragraph of subsection (4) should be accorded equal ranking.
- (6) Consent should be obtained from the person whose relationship to the person concerned is accorded the highest ranking in accordance with subsections (4) and (5).
- (7) If the relationship of each of two or more persons to the person concerned is accorded equal highest ranking in accordance with subsections (4) and (5), it is sufficient to obtain the consent of any of them.
- (8) In applying the principles set out above, a person’s relationship shall be left out of account if—
  - (a) he does not wish to deal with the issue of consent,
  - (b) he is not able to deal with that issue, or

- (c) having regard to the activity in relation to which consent is sought, it is not reasonably practicable to communicate with him within the time available if consent in relation to the activity is to be acted on.

- (9) The Secretary of State may by order amend subsection (4).

## 25 Effect of codes

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- (1) A failure on the part of any person to observe any provision of a code of practice under section 23 shall not of itself render the person liable to any proceedings.
- (2) The Authority may, in carrying out its functions with respect to licences, take into account any relevant observance of, or failure to observe, a code of practice under section 23, so far as dealing with a matter mentioned in any of paragraphs (a) to (c) and (e) to (j) of subsection (2) of that section.

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## 26 Approval of codes

- (1) Where a proposed code of practice under section 23 deals with a matter mentioned in any of paragraphs (a) to (c) and (e) to (j) of subsection (2) of that section, the Authority shall send a draft of the proposed code to the Secretary of State for approval.
- (2) Before approving a draft code of practice sent to him under subsection (1), the Secretary of State shall –
  - (a) if the code relates to Wales, consult the National Assembly for Wales, and
  - (b) if the code relates to Northern Ireland, consult the relevant Northern Ireland department.
- (3) If the Secretary of State approves a draft code of practice sent to him under subsection (1) –
  - (a) he shall lay a copy of it before each House of Parliament,
  - (b) if the code relates to Wales, he shall send a copy of it to the National Assembly for Wales,
  - (c) if the code relates to Northern Ireland, he shall send a copy of it to the relevant Northern Ireland department, and
  - (d) the code (in the form of the draft) shall come into effect on such day as may be appointed by directions.
- (4) If the Secretary of State does not approve a draft sent to him under subsection (1), he shall give reasons to the Authority.
- (5) The relevant Northern Ireland department shall lay before the Northern Ireland Assembly any document which it receives under subsection (3)(c).

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## Anatomy

## 27 Possession of anatomical specimens away from licensed premises

- (1) Subject to subsections (2) to (6), a person commits an offence if –
  - (a) he has possession of an anatomical specimen, and
  - (b) the specimen is not on premises in respect of which an anatomy licence is in force.

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- (2) Subsection (1) does not apply where—
  - (a) the specimen has come from premises in respect of which a storage licence is in force, and
  - (b) the person—
    - (i) is authorised in writing by the designated individual to have possession of the specimen, and 5
    - (ii) has possession of the specimen only for a purpose for which he is so authorised to have possession of it.
- (3) Subsection (1) does not apply where—
  - (a) the specimen is the body of a deceased person which is to be used for the purpose of anatomical examination, 10
  - (b) the person who has possession of the body has come into lawful possession of it immediately after the deceased's death, and
  - (c) he retains possession of the body prior to its removal to premises in respect of which an anatomy licence is in force. 15
- (4) Subsection (1) does not apply where the person has possession of the specimen only for the purpose of transporting it to premises—
  - (a) in respect of which an anatomy licence is in force, or
  - (b) where the specimen is to be used for the purpose of education, training or research. 20
- (5) Subsection (1) does not apply where the person has possession of the specimen for purposes of functions of, or under the authority of, a coroner.
- (6) Subsection (1) does not apply where the person reasonably believes—
  - (a) that what he has possession of is not an anatomical specimen,
  - (b) that the specimen is on premises in respect of which an anatomy licence is in force, or 25
  - (c) that any of subsections (2) to (5) applies.
- (7) A person guilty of an offence under subsection (1) shall be liable—
  - (a) on summary conviction—
    - (i) to imprisonment for a term not exceeding 12 months, or 30
    - (ii) to a fine not exceeding the statutory maximum, or
    - (iii) to both;
  - (b) on conviction on indictment—
    - (i) to imprisonment for a term not exceeding 3 years, or
    - (ii) to a fine, or 35
    - (iii) to both.
- (8) In this section—

“anatomy licence” means a licence authorising—

  - (a) the carrying-out of an anatomical examination, or
  - (b) the storage of anatomical specimens; 40

“storage licence” means a licence authorising the storage of anatomical specimens.

## 28 Possession of former anatomical specimens away from licensed premises

- (1) Subject to subsections (2) to (5), a person commits an offence if—
  - (a) he has possession of a former anatomical specimen, and 45

- (b) the specimen is not on premises in respect of which a storage licence is in force.
- (2) Subsection (1) does not apply where –
  - (a) the specimen has come from premises in respect of which a storage licence is in force, and 5
  - (b) the person –
    - (i) is authorised in writing by the designated individual to have possession of the specimen, and
    - (ii) has possession of the specimen only for a purpose for which he is so authorised to have possession of it. 10
- (3) Subsection (1) does not apply where the person has possession of the specimen only for the purpose of transporting it to premises –
  - (a) in respect of which a storage licence is in force, or
  - (b) where the specimen is to be used for the purpose of education, training or research. 15
- (4) Subsection (1) does not apply where the person has possession of the specimen –
  - (a) only for the purpose of its decent disposal, or
  - (b) for purposes of functions of, or under the authority of, a coroner.
- (5) Subsection (1) does not apply where the person reasonably believes – 20
  - (a) that what he has possession of is not a former anatomical specimen,
  - (b) that the specimen is on premises in respect of which a storage licence is in force, or
  - (c) that any of subsections (2) to (4) applies.
- (6) A person guilty of an offence under subsection (1) shall be liable – 25
  - (a) on summary conviction –
    - (i) to imprisonment for a term not exceeding 12 months, or
    - (ii) to a fine not exceeding the statutory maximum, or
    - (iii) to both;
  - (b) on conviction on indictment – 30
    - (i) to imprisonment for a term not exceeding 3 years, or
    - (ii) to a fine, or
    - (iii) to both.
- (7) In this section, “storage licence” means a licence authorising the storage, for use for a scheduled purpose, of relevant material which has come from a human body. 35

### *Trafficking*

## **29 Prohibition of commercial dealings in human material**

- (1) A person commits an offence if he –
  - (a) gives or receives a reward for the supply of, or for an offer to supply, the body of a deceased person or any relevant bodily material; 40
  - (b) seeks to find a person willing to supply the body of a deceased person, or any relevant bodily material, for reward;



- (c) offers to supply the body of a deceased person, or any relevant bodily material, for reward;
    - (d) initiates or negotiates any arrangement involving the giving of a reward for the supply of, or for an offer to supply, the body of a deceased person or any relevant bodily material; 5
    - (e) takes part in the management or control of a body of persons corporate or unincorporate whose activities consist of or include the initiation or negotiation of such arrangements.
- (2) Without prejudice to subsection (1)(b) and (c), a person commits an offence if he causes to be published or distributed, or knowingly publishes or distributes, an advertisement – 10
  - (a) inviting persons to supply, or offering to supply, for reward the body of a deceased person or any relevant bodily material, or
  - (b) indicating that the advertiser is willing to initiate or negotiate any such arrangement as is mentioned in subsection (1)(d). 15
- (3) A person who engages in an activity to which subsection (1) or (2) applies does not commit an offence under that subsection if –
  - (a) he is designated by the Authority as a person who may lawfully engage in the activity, or
  - (b) he engages in the activity for the purpose of, or in connection with, acquisition for purposes of a qualifying museum. 20
- (4) A person guilty of an offence under subsection (1) shall be liable –
  - (a) on summary conviction –
    - (i) to imprisonment for a term not exceeding 12 months, or
    - (ii) to a fine not exceeding the statutory maximum, or 25
    - (iii) to both;
  - (b) on conviction on indictment –
    - (i) to imprisonment for a term not exceeding 3 years, or
    - (ii) to a fine, or
    - (iii) to both. 30
- (5) A person guilty of an offence under subsection (2) shall be liable on summary conviction –
  - (a) to imprisonment for a term not exceeding 51 weeks, or
  - (b) to a fine not exceeding level 5 on the standard scale, or
  - (c) to both. 35
- (6) References in subsections (1) and (2) to reward, in relation to the supply of the body of a deceased person, do not include payment in money or money's worth for defraying or reimbursing any expenses incurred in, or in connection with, transporting, preserving or storing the body.
- (7) References in subsections (1) and (2) to reward, in relation to the supply of any relevant bodily material, do not include payment in money or money's worth for defraying or reimbursing – 40
  - (a) any expenses incurred in, or in connection with, transporting, removing, preparing, preserving or storing the material, or
  - (b) any expenses or loss of earnings incurred by the person from whose body the material comes so far as reasonably and directly attributable to his supplying the material from his body. 45

- (8) For the purposes of this section, “relevant bodily material” means any bodily material which –
- (a) consists of or includes human cells, and
  - (b) is not of a kind excepted under subsection (9).
- (9) The following kinds of bodily material are excepted – 5
- (a) gametes,
  - (b) embryos,
  - (c) hair and nail from the body of a living person, and
  - (d) material which is the subject of property because of an application of human skill. 10
- (10) In this section –
- “advertisement” includes any form of advertising whether to the public generally, to any section of the public or individually to selected persons;
  - “bodily material” means material from a human body; 15
  - “reward” means any description of financial or other material advantage.

### *Transplants*

## **30 Restriction on transplants involving a live donor**

- (1) Subject to subsections (3) and (5), a person commits an offence if –
- (a) he removes any transplantable material from the body of a living person intending that the material be used for the purpose of transplantation, and 20
  - (b) when he removes the material, he knows, or might reasonably be expected to know, that the person from whose body he removes the material is alive. 25
- (2) Subject to subsections (3) and (5), a person commits an offence if –
- (a) he uses for the purpose of transplantation any transplantable material which has come from the body of a living person, and
  - (b) when he does so, he knows, or might reasonably be expected to know, that the transplantable material has come from the body of a living person. 30
- (3) The Secretary of State may by regulations provide that subsection (1) or (2) shall not apply in a case where –
- (a) the Authority is satisfied –
    - (i) that no reward has been or is to be given in contravention of section 29, and
    - (ii) that such other conditions as are specified in the regulations are satisfied, and
  - (b) such other requirements as are specified in the regulations are complied with. 35
- (4) Regulations under subsection (3) shall include provision for decisions of the Authority in relation to matters which fall to be decided by it under the regulations to be subject, in such circumstances as the regulations may provide, to reconsideration in accordance with such procedure as the regulations may provide. 40
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- (5) Where under subsection (3) an exception from subsection (1) or (2) is in force, a person does not commit an offence under that subsection if he reasonably believes that the exception applies.
- (6) A person guilty of an offence under this section is liable on summary conviction –
  - (a) to imprisonment for a term not exceeding 51 weeks, or
  - (b) to a fine not exceeding level 5 on the standard scale, or
  - (c) to both.
- (7) In this section –
  - “reward” has the same meaning as in section 29;
  - “transplantable material” means material of a description specified by order made by the Authority.

### 31 Information about transplant operations

- (1) The Secretary of State may make regulations requiring such persons as may be specified in the regulations to supply to such authority as may be so specified such information as may be so specified with respect to transplants that have been or are proposed to be carried out using transplantable material removed from a human body.
- (2) Any such authority shall keep a record of information supplied to it in pursuance of regulations under this section.
- (3) A person commits an offence if –
  - (a) he fails without reasonable excuse to comply with regulations under this section, or
  - (b) in purported compliance with such regulations, he knowingly or recklessly supplies information which is false or misleading in a material respect.
- (4) A person guilty of an offence under subsection (3)(a) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.
- (5) A person guilty of an offence under subsection (3)(b) is liable on summary conviction to a fine not exceeding level 5 on the standard scale.
- (6) In this section, “transplantable material” has the same meaning as in section 30.

### *Inspectorates*

### 32 Inspectorate of Anatomy and Pathology

- (1) There shall be an Inspectorate of Anatomy and Pathology consisting of –
  - (a) a board,
  - (b) a chief executive officer appointed by the Authority, and
  - (c) such other staff of the Authority as may be assigned by the Authority to assist the board.
- (2) The chief executive officer and the other staff assigned to assist the board of the Inspectorate of Anatomy and Pathology shall be under the direction of the board.

- (3) The board of the Inspectorate of Anatomy and Pathology shall carry out on behalf of the Authority such of the Authority's functions in relation to activities within the remit of the Inspectorate as the Secretary of State may by order provide.
  - (4) The Authority may delegate to the board of the Inspectorate of Anatomy and Pathology (to such extent as it may determine) any function in relation to an activity within the remit of the Inspectorate. 5
  - (5) Schedule 4 has effect in relation to the board of the Inspectorate of Anatomy and Pathology.
- 33 Remit of Inspectorate of Anatomy and Pathology 10**
- (1) The following are the activities within the remit of the Inspectorate of Anatomy and Pathology –
    - (a) the removal from a human body, for use for a scheduled purpose other than transplantation, of relevant material of which the body consists or which it contains; 15
    - (b) the use of –
      - (i) the body of a deceased person, or
      - (ii) relevant material which has come from a human body, for a scheduled purpose other than transplantation;
    - (c) the storage of an anatomical specimen or former anatomical specimen; 20
    - (d) the storage (in any case not falling within paragraph (c)) of –
      - (i) the body of a deceased person, or
      - (ii) relevant material which has come from a human body, for use for a scheduled purpose other than transplantation;
    - (e) the import or export of – 25
      - (i) the body of a deceased person, or
      - (ii) relevant material which has come from a human body, for use for a scheduled purpose other than transplantation;
    - (f) the disposal of the body of a deceased person which has been –
      - (i) imported for use, 30
      - (ii) stored for use, or
      - (iii) used, for a scheduled purpose;
    - (g) the disposal of relevant material which –
      - (i) has been removed from a person's body for the purposes of his medical treatment, 35
      - (ii) has been removed from the body of a deceased person for the purposes of an anatomical, or post-mortem, examination,
      - (iii) has been removed from a human body (otherwise than as mentioned in sub-paragraph (ii)) for use for a scheduled purpose other than transplantation, 40
      - (iv) has come from a human body and been imported for use for a scheduled purpose other than transplantation, or
      - (v) has come from the body of a deceased person which has been imported for use for a scheduled purpose. 45



- (2) Without prejudice to the generality of subsection (1)(a) and (b), the activities within the remit of the Inspectorate of Anatomy and Pathology include, in particular –
  - (a) the carrying-out of an anatomical examination, and
  - (b) the making of a post-mortem examination.
- (3) An activity is excluded from the remit of the Inspectorate of Anatomy and Pathology if it is done for purposes of a qualifying museum.
- (4) The Secretary of State may by order amend this section for the purpose of adding to the activities within the remit of the Inspectorate of Anatomy and Pathology an activity within the remit of the Authority.

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### **34 Inspectorate of Organ and Tissue for Human Use**

- (1) There shall be an Inspectorate of Organ and Tissue for Human Use consisting of –
  - (a) a board,
  - (b) a chief executive officer appointed by the Authority, and
  - (c) such other staff of the Authority as may be assigned by the Authority to assist the board.
- (2) The chief executive officer and the other staff assigned to assist the board of the Inspectorate of Organ and Tissue for Human Use shall be under the direction of the board.
- (3) The board of the Inspectorate of Organ and Tissue for Human Use shall carry out on behalf of the Authority such of the Authority's functions in relation to activities within the remit of the Inspectorate as the Secretary of State may by order provide.
- (4) The Authority may delegate to the board of the Inspectorate of Organ and Tissue for Human Use (to such extent as it may determine) any function in relation to an activity within the remit of the Inspectorate.
- (5) Schedule 4 has effect in relation to the board of the Inspectorate of Organ and Tissue for Human Use.

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### **35 Remit of Inspectorate of Organ and Tissue for Human Use**

- (1) The following are the activities within the remit of the Inspectorate of Organ and Tissue for Human Use –
  - (a) the removal from a human body, for use for the purpose of transplantation, of relevant material of which the body consists or which it contains;
  - (b) the use, for the purpose of transplantation, of relevant material which has come from a human body;
  - (c) the storage, for use for the purpose of transplantation, of relevant material which has come from a human body;
  - (d) the import or export, for use for the purpose of transplantation, of relevant material which has come from a human body;
  - (e) the disposal of relevant material which –
    - (i) has been removed from a human body for use for the purpose of transplantation, or

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- (ii) has come from a human body and been imported for use for the purpose of transplantation.
- (2) The Secretary of State may by order amend this section for the purpose of adding to the activities within the remit of the Inspectorate of Organ and Tissue for Human Use an activity within the remit of the Authority. 5
- (3) In this section, “relevant material” does not include blood or anything derived from blood.

### 36 Duties in relation to discharge of functions by Inspectorates

- (1) In carrying out functions of the Authority, each of the Inspectorates shall have regard to the general principles which the Authority has for the time being stated for the purposes of section 12(a)(ii). 10
- (2) The Authority shall monitor the carrying-out of functions by each of the Inspectorates.
- (3) The Authority shall establish a procedure for dealing with complaints in relation to the carrying-out of functions by each of the Inspectorates. 15

#### General

### 37 Agency arrangements and provision of services

- (1) Arrangements may be made between the Authority and a government department, a public authority or the holder of a public office (“the other authority”) for— 20
  - (a) any functions of the Authority to be carried out by, or by members of staff of, the other authority, or
  - (b) the provision by the other authority of administrative, professional or technical services to the Authority.
- (2) Arrangements under subsection (1)(a) shall not affect responsibility for the carrying-out of the Authority’s functions. 25
- (3) Subsection (1)(a) shall not apply to functions of making subordinate legislation (within the meaning of the Interpretation Act 1978 (c. 30)).

### 38 Annual report

- (1) The Authority shall prepare— 30
  - (a) a report for the first twelve months of its existence, and
  - (b) a report for each succeeding period of twelve months.
- (2) A report under this section shall deal with the activities of the Authority and the Inspectorates in the period to which the report relates.
- (3) The Authority shall send each report under this section— 35
  - (a) to the Secretary of State,
  - (b) to the National Assembly for Wales, and
  - (c) to the relevant Northern Ireland department,
 as soon as practicable after the end of the period to which the report relates.



- (4) The Secretary of State shall lay a copy of each report received by him under this section before each House of Parliament.
- (5) The relevant Northern Ireland department shall lay a copy of each report received by it under this section before the Northern Ireland Assembly.

### 39 Directions

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- (1) The Authority may give directions for any purpose for which directions may be given under this Part.
- (2) Any power under this Part to give directions includes power to vary or revoke directions given in previous exercise of the power.
- (3) Any power under this Part to give directions is exercisable by instrument in writing. 10
- (4) Directions under this Part to a particular person shall be given by serving notice of the directions on the person.
- (5) Directions under this Part in respect of any licence (including one which has ceased to have effect) may be given— 15
  - (a) by serving notice of the directions on the person who is (or was immediately before the cessation) the designated individual or holder of the licence, or
  - (b) if it appears to the Authority that it is not practicable to give notice in that way, by publishing the directions in such way as, in its opinion, is likely to bring them to the attention of the persons to whom they are applicable. 20
- (6) Directions under this Part which appear to the Authority to be general directions may be given by publishing them as mentioned in subsection (5)(b).
- (7) This section does not apply to directions under Schedule 2. 25

### *Exceptions*

### 40 Criminal justice purposes

- (1) Subject to subsection (2), nothing in section 11(1), 13(2) or 33(1) applies to anything done for purposes related to— 30
  - (a) the prevention or detection of crime, or
  - (b) the conduct of a prosecution.
- (2) Subsection (1) does not except from section 11(1), 13(2) or 33(1) the carrying-out of a post-mortem examination for purposes of functions of a coroner.
- (3) The reference in subsection (2) to the carrying-out of a post-mortem examination does not include the removal of relevant material from the body of a deceased person, or from a part of the body of a deceased person, at the place where the body or part is first found by a constable. 35
- (4) For the purposes of subsection (1)(a), detecting crime shall be taken to include— 40
  - (a) establishing by whom, for what purpose, by what means and generally in what circumstances any crime was committed, and
  - (b) the apprehension of the person by whom any crime was committed;

and the reference in subsection (1)(a) to the detection of crime includes any detection outside the United Kingdom of any crime or suspected crime.

- (5) In subsection (1)(b), the reference to a prosecution includes a prosecution brought in respect of any crime in a country or territory outside the United Kingdom. 5
- (6) In this section, references to crime include a reference to any conduct which –
  - (a) constitutes one or more criminal offences (whether under the law of a part of the United Kingdom or of a country or territory outside the United Kingdom),
  - (b) is, or corresponds to, any conduct which, if it all took place in any one part of the United Kingdom, would constitute one or more criminal offences, or 10
  - (c) constitutes one or more offences of a kind triable by court-martial under the Army Act 1955 (3 & 4 Eliz. 2 c. 18), the Air Force Act 1955 (3 & 4 Eliz. 2 c. 19) or the Naval Discipline Act 1957 (c. 53). 15

#### 41 Religious relics

- (1) This section applies –
  - (a) to the use of –
    - (i) the body of a deceased person, or
    - (ii) relevant material which has come from a human body, 20
 for the purpose of public display at a place of public religious worship or at a place associated with such a place, and
  - (b) to the storage of –
    - (i) the body of a deceased person, or
    - (ii) relevant material which has come from a human body, 25
 for use for the purpose mentioned in paragraph (a).
- (2) An activity to which this section applies is excluded from sections 11(1), 13(2) and 33(1) if there is a connection between –
  - (a) the body or material to which the activity relates, and
  - (b) the religious worship which takes place at the place of public religious worship concerned. 30
- (3) For the purposes of this section, a place is associated with a place of public religious worship if it is used for purposes associated with the religious worship which takes place there.

*Supplementary* 35

#### 42 “Qualifying museum”

- (1) For the purposes of this Part, a museum is a “qualifying museum” if –
  - (a) it has a permanent collection that is open to the public, and
  - (b) it is, or is maintained by, an eligible institution.
- (2) In this Part, references to purposes of a qualifying museum, where the qualifying museum is maintained by an eligible institution, are to purposes of the institution which maintains the museum, so far as relating to the museum. 40
- (3) In this section, “eligible institution” means an institution which –



- (a) does not make profits,
- (b) is precluded from distributing any profits it makes, or
- (c) may distribute any profits it makes only to eligible institutions.

#### 43 Interpretation of Part 2

- (1) In this Part—
  - “anatomical specimen” means—
    - (a) the body of a deceased person to be used for the purpose of anatomical examination, or
    - (b) the body of a deceased person in the course of being used for the purpose of anatomical examination (including separated parts of such a body);
  - “appeals committee” has the meaning given by section 17(2);
  - “designated individual”, in relation to a licence, means the individual designated in the licence as the person under whose supervision the licensed activity is authorised to be carried on;
  - “export” means export from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland;
  - “import” means import into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland;
  - “the Inspectorates” means the Inspectorate of Anatomy and Pathology and the Inspectorate of Organ and Tissue for Human Use;
  - “scheduled purpose” means a purpose specified in Schedule 1.
- (2) In this Part, references to a person to whom a licence applies are to a person to whom the authority conferred by the licence extends (as provided by section 14).

### PART 3

#### MISCELLANEOUS AND GENERAL

##### *Miscellaneous*

#### 44 Preservation for transplantation

- (1) Where part of a body lying in a hospital, nursing home or other institution is or may be suitable for use for transplantation, it shall be lawful for the person having the control and management of the institution—
  - (a) to take steps for the purpose of preserving the part for use for transplantation, and
  - (b) to retain the body for that purpose.
- (2) Authority under subsection (1)(a) shall only extend—
  - (a) to the taking of the minimum steps necessary for the purpose mentioned in that provision, and
  - (b) to the use of the least invasive procedure.
- (3) Authority under subsection (1) ceases to apply once it has been established that consent making removal of the part for transplantation lawful has not been, and will not be, given.

- (4) Authority under subsection (1) shall extend to any person authorised to act under the authority by –
  - (a) the person on whom the authority is conferred by that subsection, or
  - (b) a person authorised under this subsection to act under the authority.
- (5) In this section, “body” means the body of a deceased person. 5

#### 45 Surplus tissue

- (1) It shall be lawful for material to which subsection (2) or (3) applies to be dealt with as waste.
- (2) This subsection applies to any material which consists of or includes human cells and which has come from a person’s body in the course of his – 10
  - (a) receiving medical treatment,
  - (b) undergoing diagnostic testing, or
  - (c) participating in research.
- (3) This subsection applies to any relevant material which – 15
  - (a) has come from a human body, and
  - (b) ceases to be used, or stored for use, for a purpose specified in Schedule 1.
- (4) This section shall not be read as making unlawful anything which is lawful apart from this section.

#### 46 Offences relating to non-consensual analysis of DNA 20

- (1) A person commits an offence if –
  - (a) he has any bodily material intending –
    - (i) that any human DNA in the material be analysed without qualifying consent, and
    - (ii) that the results of the analysis be used otherwise than for excepted purposes (see section 47), 25
  - (b) the material is not of a kind excepted under subsection (2), and
  - (c) he does not reasonably believe the material to be of a kind so excepted.
- (2) Bodily material is excepted if –
  - (a) it is material which has come from the body of a person who died before the day on which this section comes into force and at least one hundred years have elapsed since the date of the person’s death, or 30
  - (b) it is an embryo outside the human body.
- (3) A person guilty of an offence under this section –
  - (a) is liable on summary conviction – 35
    - (i) to imprisonment for a term not exceeding 12 months, or
    - (ii) to a fine not exceeding the statutory maximum, or
    - (iii) to both;
  - (b) is liable on conviction on indictment –
    - (i) to imprisonment for a term not exceeding 3 years, or 40
    - (ii) to a fine, or
    - (iii) to both.



- (4) Schedule 5 (which makes provision about what constitutes qualifying consent for the purposes of this section) has effect.
- (5) In this section, “bodily material” means material which –
  - (a) has come from a human body, and
  - (b) consists of or includes human cells.

5

#### 47 Purposes for which DNA may be analysed without consent

- (1) In any case, the following are excepted purposes for the purposes of section 46(1)(a)(ii) –
  - (a) purposes of medical diagnosis or treatment of the person whose body manufactured the DNA; 10
  - (b) purposes of functions of a coroner;
  - (c) purposes of functions of a procurator fiscal in connection with the investigation of deaths;
  - (d) purposes of –
    - (i) the prevention or detection of crime, or 15
    - (ii) the conduct of a prosecution;
  - (e) purposes of national security;
  - (f) purposes of implementing an order or direction of a court or tribunal, including one outside the United Kingdom.
- (2) In a case where the material is from the body of a living person, the following are also excepted purposes for the purposes of section 46(1)(a)(ii) – 20
  - (a) purposes of clinical audit;
  - (b) purposes of education or training which is incidental to medical diagnosis or treatment;
  - (c) purposes of public health monitoring; 25
  - (d) purposes of quality assurance.
- (3) For the purposes of subsection (1)(d)(i), detecting crime shall be taken to include –
  - (a) establishing by whom, for what purpose, by what means and generally in what circumstances any crime was committed, and 30
  - (b) the apprehension of the person by whom any crime was committed;
 and the reference in subsection (1)(d)(i) to the detection of crime includes any detection outside the United Kingdom of any crime or suspected crime.
- (4) In subsection (1)(d)(ii), the reference to a prosecution includes a prosecution brought in respect of any crime in a country or territory outside the United Kingdom. 35
- (5) In this section, a reference to crime includes a reference to any conduct which –
  - (a) constitutes one or more criminal offences (whether under the law of a part of the United Kingdom or of a country or territory outside the United Kingdom), 40
  - (b) is, or corresponds to, conduct which, if it all took place in any one part of the United Kingdom, would constitute one or more criminal offences, or
  - (c) constitutes one or more offences of a kind triable by court-martial under the Army Act 1955 (3 & 4 Eliz. 2 c. 18), the Air Force Act 1955 45 (3 & 4 Eliz. 2 c. 19) or the Naval Discipline Act 1957 (c. 53).

- (6) Subsection (1)(f) shall not be taken to confer any power to make orders or give directions.
- (7) The Secretary of State may by order amend the preceding provisions of this section for the purpose of—
  - (a) varying or omitting any of the purposes specified in subsection (1) or (2), or
  - (b) adding to the purposes so specified.

#### 48 Power to give effect to Community obligations

- (1) The Secretary of State may by regulations amend this Act—
  - (a) for the purpose of implementing a relevant obligation or enabling a relevant obligation to be implemented, or
  - (b) for the purpose of dealing with matters arising out of or related to a relevant obligation.
- (2) The power under subsection (1) —
  - (a) includes (in particular) power to add or omit provisions, and
  - (b) includes power consequentially to amend or repeal any other enactment and any instrument made under an enactment.
- (3) In this section, “relevant obligation” means a Community obligation of the United Kingdom relating to material which consists of, includes or is derived from human cells.

#### 49 Power to de-accession human remains

- (1) This section applies to the following bodies —
  - The Board of Trustees of the Armouries
  - The Trustees of the British Museum
  - The Trustees of the Imperial War Museum
  - The Board of Governors of the Museum of London
  - The Trustees of the National Maritime Museum
  - The Board of Trustees of the National Museums and Galleries on Merseyside
  - The Trustees of the Natural History Museum
  - The Board of Trustees of the Science Museum
  - The Board of Trustees of the Victoria and Albert Museum.
- (2) Any body to which this section applies may transfer from their collection any human remains if it appears to them to be appropriate to do so for any reason, whether or not relating to their other functions.
- (3) If, in relation to any human remains in their collection, it appears to a body to which this section applies —
  - (a) that the human remains are mixed or bound up with something other than human remains, and
  - (b) that it is undesirable, or impracticable, to separate them,
 the power conferred by subsection (2) includes power to transfer the thing with which the human remains are mixed or bound up.



- (4) The power conferred by subsection (2) does not affect any trust or condition subject to which a body to which this section applies holds anything in relation to which the power is exercisable.
- (5) The power conferred by subsection (2) is an additional power.

*General*

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**50 Powers of inspection, entry, search and seizure**

Schedule 6 (which makes provision about powers of inspection, entry, search and seizure for the purposes of this Act) has effect.

**51 Offences by bodies corporate**

- (1) Where an offence under this Act is committed by a body corporate and is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of –
  - (a) any director, manager, secretary or other similar officer of the body corporate, or
  - (b) any person who was purporting to act in any such capacity,  
he (as well as the body corporate) commits the offence and shall be liable to be proceeded against and punished accordingly.
- (2) Where the affairs of a body corporate are managed by its members, subsection (1) applies in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.
- (3) Where an offence under this Act is committed by a Scottish partnership and is proved to have been committed with the consent or connivance of a partner, or to be attributable to any neglect on the part of a partner, he (as well as the partnership) commits the offence and shall be liable to be proceeded against and punished accordingly.
- (4) In subsection (3), “partner” includes a person purporting to act as a partner.

**52 Prosecutions**

No proceedings for an offence under section 5, 29 or 30 shall be instituted –

- (a) in England and Wales, except by or with the consent of the Director of Public Prosecutions;
- (b) in Northern Ireland, except by or with the consent of the Director of Public Prosecutions for Northern Ireland.

**53 Offences: Northern Ireland and Scotland**

- (1) This Act has effect in relation to Northern Ireland with the modifications specified in subsections (2) and (3).
- (2) In sections 29(5)(a) and 30(6)(a), for “51 weeks” there is substituted “6 months”.
- (3) In sections 5(6)(a)(i), 6(3)(a)(i), 22(2)(a)(i), 27(7)(a)(i), 28(6)(a)(i), 29(4)(a)(i) and 46(3)(a)(i), for “12 months” there is substituted “6 months”.

- (4) Section 46 has effect in relation to Scotland with the substitution in subsection (3)(a)(i) of “6 months” for “12 months”.

## 54 Orders and regulations

- (1) Any power to make orders or regulations under this Act includes power –  
 (a) to make different provision for different cases, and 5  
 (b) to make incidental, supplementary, consequential or transitional provision or savings.
- (2) Any power to make orders or regulations under this Act is exercisable by statutory instrument.
- (3) A statutory instrument containing an order or regulations under this Act, except sections 1(8), 8(9), 11(4), 13(5), 24(9), 30(3), 33(4), 35(2), 47(7), 48(1) and 56(10), made by the Secretary of State shall be subject to annulment in pursuance of a resolution of either House of Parliament. 10
- (4) No order under section 1(8), 8(9), 11(4), 24(9), 33(4), 35(2), 47(7) or 56(10), and no regulations under section 13(5), 30(3) or 48(1), shall be made unless a draft of the statutory instrument containing it, or them, has been laid before and approved by a resolution of each House of Parliament. 15
- (5) Subsections (1) to (3) do not apply to orders under section 60 or 62.
- (6) The power under section 11(4), 13(5) or 33(4) –  
 (a) so far as relating to museums in Wales, may only be exercised with the consent of the National Assembly for Wales, and 20  
 (b) so far as relating to museums in Northern Ireland, may only be exercised with the consent of the Department of Culture, Arts and Leisure.
- (7) The Secretary of State shall consult the National Assembly for Wales and the relevant Northern Ireland department before acting under any of the following provisions – 25
- section 1(8);  
 section 4(10)(b);  
 section 6(4)(d); 30  
 section 8(9);  
 section 11(4);  
 section 13(3) and (5);  
 section 24(9);  
 section 30(3); 35  
 section 31(1);  
 section 32(3);  
 section 33(4);  
 section 34(3);  
 section 35(2); 40  
 section 47(7);  
 section 48(1);  
 section 56(10);  
 paragraph 4(5) of Schedule 6.



- (8) Before acting under section 47(7), the Secretary of State shall also consult the Scottish Ministers.

## 55 “Relevant material”

- (1) In this Act, “relevant material” means material, other than gametes, which consists of or includes human cells. 5
- (2) In this Act, references to relevant material from a human body do not include—
- (a) embryos outside the human body, or
  - (b) hair and nail from the body of a living person.

## 56 General interpretation

- (1) In this Act— 10
- “adult” means a person who has attained the age of 18 years;
  - “anatomical examination” means examination by dissection for anatomical purposes;
  - “anatomical purposes” means purposes of teaching or studying, or researching into, morphology; 15
  - “the Authority” has the meaning given by section 10(1);
  - “child”, except in subsection (9), means a person who has not attained the age of 18 years;
  - “licence” means a licence under paragraph 1 of Schedule 3;
  - “licensed activity”, in relation to a licence, means the activity which the licence authorises to be carried on; 20
  - “parental responsibility”—
    - (a) in relation to England and Wales, has the same meaning as in the Children Act 1989 (c. 41), and
    - (b) in relation to Northern Ireland, has the same meaning as in the Children (Northern Ireland) Order 1995 (S.I. 1995/755 (N.I. 2)); 25
  - “relevant Northern Ireland department” means the Department of Health, Social Services and Public Safety.
- (2) In this Act, references to the carrying-out of an anatomical examination are to the carrying-out of an examination by dissection for anatomical purposes of the body of a deceased person, and, where parts of the body of a deceased person are separated in the course of such an examination, include the carrying-out of an examination by dissection of the parts for those purposes. 30
- (3) In this Act—
- (a) references to material from the body of a living person are to material from the body of a person alive at the point of separation, and 35
  - (b) references to material from the body of a deceased person are to material from the body of a person not alive at the point of separation.
- (4) In this Act, references to transplantation are to transplantation into a human body and include transfusion. 40
- (5) In this Act, references to decent disposal include, in relation to disposal of material which has come from a human body, disposal as waste.
- (6) Subsections (1) and (4) of section 1 of the Human Fertilisation and Embryology Act 1990 (c. 37) (definitions of “embryo” and “gametes”) have effect for the

- purposes of this Act as they have effect for the purposes of that Act (other than that section).
- (7) For the purposes of this Act, material shall not be regarded as from a human body if it is created outside the human body.
- (8) For the purposes of this Act, except section 51, a person is another's partner if the two of them (whether of different sexes or the same sex) live as partners in an enduring family relationship. 5
- (9) The following are qualifying relationships for the purposes of this Act, spouse, partner, parent, child, brother, sister, child of a brother or sister, stepfather, stepmother, half-brother, half-sister and friend of long standing. 10
- (10) The Secretary of State may by order amend subsection (9).
- 57 Financial provisions**
- There shall be paid out of money provided by Parliament –*
- (a) *any expenditure incurred by the Secretary of State in consequence of this Act, and* 15
- (b) *any increase attributable to this Act in the sums payable out of money so provided under any other enactment.*
- 58 Consequential amendments**
- Schedule 7 (consequential amendments) has effect.
- 59 Repeals and revocations** 20
- The enactments and instruments specified in Schedule 8 are hereby repealed or revoked to the extent specified.
- 60 Transition**
- (1) In relation to an offence committed before the commencement of section 154(1) of the Criminal Justice Act 2003, the reference in each of sections 5(6)(a)(i), 6(3)(a)(i), 22(2)(a)(i), 27(7)(a)(i), 28(6)(a)(i), 29(4)(a)(i) and 46(3)(a)(i) to 12 months is to be read as a reference to 6 months. 25
- (2) In relation to an offence committed before the commencement of section 281(5) of the Criminal Justice Act 2003, the reference in each of sections 29(5)(a) and 30(6)(a) to 51 weeks is to be read as a reference to 6 months. 30
- (3) The Secretary of State may by order made by statutory instrument make in connection with the coming into force of any provision of this Act such transitional provision or savings as he considers necessary or expedient.
- (4) The power under subsection (3) includes power to make different provision for different cases. 35
- (5) Before making provision under subsection (3) in connection with the coming into force in England and Wales of any provision of this Act, except section 49, the Secretary of State shall consult the National Assembly for Wales.



- (6) Before making provision under subsection (3) in connection with the coming into force in Northern Ireland of any provision of this Act, except section 49, the Secretary of State shall consult the relevant Northern Ireland department.
- (7) Before making provision under subsection (3) in connection with the coming into force in Scotland of any provision of this Act, except section 49, the Secretary of State shall consult the Scottish Ministers. 5

## 61 Extent

- (1) Subject to the following provisions, this Act extends to England and Wales and Northern Ireland only.
- (2) Sections 60(1), (2) and (5) and 62(3) extend to England and Wales only. 10
- (3) Sections 53(1) to (3), 60(6) and 62(4) extend to Northern Ireland only.
- (4) The following provisions also extend to Scotland –
  - (a) sections 46(1) to (3) and (5), 47 and 49,
  - (b) section 51 so far as having effect for the purposes of section 46,
  - (c) section 54 so far as relating to orders under section 47(7), 15
  - (d) section 56(3)(a) so far as having effect for the purposes of section 47,
  - (e) section 56(6) and (7) so far as having effect for the purposes of section 46, and
  - (f) section 60(3) and (4), this section and sections 62(1) and (2) and 63.
- (5) The following provisions extend to Scotland only – 20
  - (a) sections 53(4), 60(7) and 62(5),
  - (b) Part 2 of Schedule 5, and section 46(4) so far as relating thereto, and
  - (c) paragraphs 2 and 4 of Schedule 7, and section 58 so far as relating thereto.
- (6) Subject to subsection (5), any amendment made by this Act has the same extent as the enactment to which it relates. 25
- (7) Subject to subsection (8), any repeal or revocation made by this Act has the same extent as the enactment or instrument to which it relates.
- (8) Except as provided by subsection (9), the repeals of the following do not extend to Scotland – 30
  - (a) the Human Tissue Act 1961 (c. 54),
  - (b) the Anatomy Act 1984 (c. 14),
  - (c) the Corneal Tissue Act 1986 (c. 18), and
  - (d) the Human Organ Transplants Act 1989 (c. 31).
- (9) The repeals of the following provisions do extend to Scotland – 35
  - (a) in section 1(4A)(b) of the Human Tissue Act 1961, the words “, Primary Care Trust”;
  - (b) in section 1(10) of that Act –
    - (i) paragraph (a) of the definition of “health authority”,
    - (ii) in the definition of “NHS trust”, the words “the National Health Service and Community Care Act 1990 or”, and 40
    - (iii) the words after the definition of that expression;
  - (c) section 4(5) of the Anatomy Act 1984;
  - (d) in the Human Organ Transplants Act 1989 –

- (i) in section 1, the words “in Great Britain”, in the first and third places where they occur,
- (ii) in sections 2 and 3, the words “in Great Britain”, in each place, and
- (iii) sections 5 and 6.

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## 62 Commencement

- (1) The following provisions shall come into force on the day on which this Act is passed –
  - this section, and
  - sections 60(3) to (7), 61 and 63.
- (2) The remaining provisions of this Act shall come into force on such day as the Secretary of State may appoint by order made by statutory instrument, and different days may be so appointed for different purposes.
- (3) Before exercising the power under subsection (2) in relation to the coming into force in England and Wales of any provision of this Act, except section 49, the Secretary of State shall consult the National Assembly for Wales.
- (4) Before exercising the power under subsection (2) in relation to the coming into force in Northern Ireland of any provision of this Act, except section 49, the Secretary of State shall consult the relevant Northern Ireland department.
- (5) Before exercising the power under subsection (2) in relation to the coming into force in Scotland of any provision of this Act, except section 49, the Secretary of State shall consult the Scottish Ministers.

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## 63 Short title

This Act may be cited as the Human Tissue Act 2004.

## SCHEDULES

### SCHEDULE 1

Section 1

#### SCHEDULED PURPOSES

##### PART 1

##### PURPOSES NORMALLY REQUIRING CONSENT

5

- |   |  |    |
|---|--|----|
| 1 | Anatomical examination.  |    |
| 2 | Determining the cause of death.  |    |
| 3 | Education or training relating to—<br>(a) human health, or<br>(b) research in connection with disorders, or the functioning, of the human body,<br>other than education or training which is incidental to medical diagnosis or treatment. | 10 |
| 4 | Establishing after a person's death the efficacy of any drug or other treatment administered to him.   | 15 |
| 5 | Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person).   |    |
| 6 | Public display.  |    |
| 7 | Research in connection with disorders, or the functioning, of the human body.  | 20 |
| 8 | Transplantation.   |    |

##### PART 2

##### PURPOSES NOT NORMALLY REQUIRING CONSENT

- |    |  |    |
|----|--|----|
| 9  | Clinical audit.  | 25 |
| 10 | Education or training which is incidental to medical diagnosis or treatment. |    |
| 11 | Public health monitoring.  |    |
| 12 | Quality assurance.   |    |



## SCHEDULE 2

Section 10

## THE HUMAN TISSUE AUTHORITY

*Membership*

- 1 (1) The Authority shall consist of—
  - (a) a chairman appointed by the Secretary of State, 5
  - (b) such number of other members appointed by the Secretary of State as the Secretary of State thinks fit,
  - (c) a member appointed by the National Assembly for Wales, and
  - (d) a member appointed by the relevant Northern Ireland department.
- (2) The Secretary of State shall exercise his power to appoint members of the Authority to secure that at all times not less than half of the members are persons who do not have, and have not had, a professional interest in any of the kinds of activity within the remit of the Authority. 10

*Disqualification*

- 2 A person is disqualified for being appointed as chairman of the Authority if he has, or has had, a professional interest in any of the kinds of activity within the remit of the Authority. 15
- 3 (1) A person is disqualified for being appointed as chairman or other member of the Authority if—
  - (a) he is the subject of a bankruptcy restrictions order or interim order, 20
  - (b) a bankruptcy order has been made against him by a court in Northern Ireland, his estate has been sequestrated by a court in Scotland or, under the law of Northern Ireland or Scotland, he has made a composition or arrangement with, or granted a trust deed for, his creditors, or 25
  - (c) in the last five years he has been convicted in the United Kingdom, the Channel Islands or the Isle of Man of an offence and has had a qualifying sentence passed on him.
- (2) Where a person is disqualified under sub-paragraph (1)(b) because a bankruptcy order has been made against him or his estate has been sequestrated, the disqualification shall cease—
  - (a) on his obtaining a discharge, or
  - (b) if the bankruptcy order is annulled or the sequestration of his estate is recalled or reduced, on the date of that event. 30
- (3) Where a person is disqualified under sub-paragraph (1)(b) because of his having made a composition or arrangement with, or granted a trust deed for, his creditors, the disqualification shall cease—
  - (a) at the end of the period of five years beginning with the date on which the terms of the deed of composition or arrangement or trust deed are fulfilled, or 40
  - (b) if, before then, he pays his debts in full, on the date on which the payment is completed.
- (4) For the purposes of sub-paragraph (1)(c), the date of conviction shall be taken to be the ordinary date on which the period allowed for making an appeal or application expires or, if an appeal or application is made, the date 45

on which the appeal or application is finally disposed of or abandoned or fails by reason of its non-prosecution.

- (5) In sub-paragraph (1)(c), the reference to a qualifying sentence is to a sentence of imprisonment for a period of not less than three months (whether suspended or not) without the option of a fine.

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### *Tenure of office*

- 4 Subject to the following provisions of this Schedule, the chairman and other members of the Authority shall hold and vacate office in accordance with the terms of their respective appointments.

- 5 (1) The terms of appointment of the chairman and other members of the Authority shall be such as the Secretary of State may determine, subject to sub-paragraph (2).

10

- (2) Appointment as chairman or other member shall be for a term not exceeding three years.

- 6 Previous service as chairman or other member of the Authority does not affect a person's eligibility for appointment to either office.

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- 7 A person holding office as chairman or other member of the Authority may resign that office by giving notice in writing to the person who appointed him.

- 8 A person holding office as chairman or other member of the Authority shall cease to hold that office if he ceases to be qualified for appointment to it.

20

- 9 A person may be removed from office as chairman or other member of the Authority by the person who appointed him if that person is satisfied that he –

- (a) has been absent from meetings of the Authority for six consecutive months, or longer, without the permission of the Authority, or  
(b) is unable or unfit to carry out his functions as chairman or other member.

25

### *Remuneration and pensions of members*

- 10 (1) The Authority may pay to the chairman or any of the other members of the Authority such remuneration as the Secretary of State may determine.

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- (2) The Authority may pay, or make provision for paying, to or in respect of the chairman or any of the other members of the Authority such pensions, allowances, fees, expenses or gratuities as the Secretary of State may determine.

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- (3) The Authority may make a payment to a person who ceases to hold office as chairman or other member of the Authority otherwise than on the expiry of his term of office if it appears to the Secretary of State that there are special circumstances which make it right for that person to receive compensation.

- (4) A payment under sub-paragraph (3) shall be of such amount as the Secretary of State may determine.

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*Staff*

- 11 The Authority may appoint such staff as it considers appropriate, on such terms and conditions as it may determine.

*Proceedings*

- 12 Subject to any provision of this Act, the Authority may regulate its own procedure (including quorum). 5
- 13 The validity of any proceedings of the Authority shall not be affected by –
- (a) any vacancy in the office of –
    - (i) chairman,
    - (ii) member appointed by the National Assembly for Wales, or 10
    - (iii) member appointed by the relevant Northern Ireland department,
  - (b) any defect in a person's appointment as chairman or other member, or
  - (c) the composition for the time being of the membership of the 15  
Authority.

*Members' interests*

- 14 (1) The Authority shall establish and maintain a system for the declaration and registration of private interests of its members.
- (2) The Authority shall publish entries recorded in the register of members' interests. 20

*Finance*

- 15 *The Secretary of State may out of money provided by Parliament make payments to the Authority of such amounts, at such times and on such conditions (if any) as he considers appropriate.* 25

*Accounts and audit*

- 16 (1) The Authority shall keep proper accounts and proper records in relation to its accounts.
- (2) The Authority shall prepare a statement of accounts in respect of each of its financial years. 30
- (3) Any such statement of accounts must comply with any directions given by the Secretary of State with the approval of the Treasury as to –
- (a) the information to be contained in it,
  - (b) the manner in which that information is to be presented, and
  - (c) the methods and principles according to which the statement is to be 35  
prepared.
- (4) The Authority shall send a copy of each statement of accounts required by sub-paragraph (2) to –
- (a) the Secretary of State,
  - (b) the National Assembly for Wales, 40
  - (c) the relevant Northern Ireland department, and



- (d) the Comptroller and Auditor General,  
before the end of such period after the end of the financial year to which the statement relates as the Secretary of State may specify by notice given to the Authority.
- (5) The relevant Northern Ireland department shall lay before the Northern Ireland Assembly each statement of accounts received by it under sub-paragraph (4). 5
- (6) The Comptroller and Auditor General shall—
- (a) examine, certify and report on each statement of accounts received by him under sub-paragraph (4), and 10
- (b) lay a copy of each such statement of accounts, and of his report on it, before each House of Parliament.
- (7) The power under sub-paragraph (3) to give directions includes power to vary or revoke directions given in previous exercise of the power.
- (8) In this paragraph “financial year” means— 15
- (a) the period beginning with the date on which the Authority is established and ending with the next 31st March, and
- (b) each successive period of 12 months ending with 31st March.

#### *Instruments*

- 17 The application of the seal of the Authority shall be authenticated by the signature of any member of the Authority or of any other person who has been authorised for the purpose by the Authority, whether generally or specially. 20
- 18 A document purporting—
- (a) to be duly executed under the seal of the Authority, or 25
- (b) to be signed on its behalf,
- shall be received in evidence and be taken, without further proof, to be so executed or signed unless the contrary is shown.

#### *Status*

- 19 (1) The Authority is not to be regarded as the servant or agent of the Crown, or as enjoying any status, privilege or immunity of the Crown. 30
- (2) The property of the Authority is not to be regarded as property of, or property held on behalf of, the Crown.

#### *Supplementary powers*

- 20 The Authority may do anything which is calculated to facilitate, or is conducive or incidental to, the carrying-out of its functions, but may not borrow money. 35

#### *Application of Statutory Instruments Act 1946*

- 21 The Statutory Instruments Act 1946 (c. 36) shall apply to any power to make orders or regulations conferred by an Act on the Authority as if the Authority were a Minister of the Crown. 40

*Public records*

- 22 In Schedule 1 to the Public Records Act 1958 (c. 51) (definition of public records), in Part 2 of the Table at the end of paragraph 3 the following entry is inserted at the appropriate place –

“Human Tissue Authority.”

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*Investigation by Parliamentary Commissioner*

- 23 In Schedule 2 to the Parliamentary Commissioner Act 1967 (c. 13) (departments and authorities subject to investigation), the following entry is inserted at the appropriate place –

“Human Tissue Authority.”

10

*House of Commons Disqualification*

- 24 In Part 2 of Schedule 1 to the House of Commons Disqualification Act 1975 (c. 24) (bodies of which all members are disqualified), the following entry is inserted at the appropriate place –

“The Human Tissue Authority.”

15

*Northern Ireland Assembly Disqualification*

- 25 In Part 2 of Schedule 1 to the Northern Ireland Assembly Disqualification Act 1975 (c. 25) (bodies of which all members are disqualified), the following entry is inserted at the appropriate place –

“The Human Tissue Authority.”

20

*Freedom of information*

- 26 In Part 6 of Schedule 1 to the Freedom of Information Act 2000 (c. 36) (public authorities), the following entry is inserted at the appropriate place –

“The Human Tissue Authority.”

## SCHEDULE 3

## Section 13

25

## LICENCES FOR THE PURPOSES OF SECTION 13

*Power to grant licence*

- 1 The Authority may on application grant a licence for the purposes of section 13.

*Characteristics of licence*

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- 2 (1) A licence shall not authorise the carrying-on of more than one activity to which section 13 applies.  
(2) A licence shall –

- (a) specify the premises where the licensed activity is authorised to be carried on, and
    - (b) designate an individual as the person under whose supervision the licensed activity is authorised to be carried on.
  - (3) A licence shall not authorise the licensed activity to be carried on – 5
    - (a) on premises at different places, or
    - (b) under the supervision of more than one individual.
  - (4) It shall be a condition of a licence –
    - (a) that the licensed activity shall be carried on only on the premises specified in the licence; 10
    - (b) that the licensed activity shall be carried on only under the supervision of the individual designated in the licence as the person under whose supervision it is authorised to be carried on;
    - (c) that such information about such matters relating to the carrying-on of the licensed activity as may be specified in directions shall be recorded in such form as may be so specified; 15
    - (d) that any record made for the purposes of the condition in paragraph (c) shall be kept until the end of such period as may be specified in directions;
    - (e) that there shall be provided to such person and at such intervals as may be specified in directions – 20
      - (i) such copies of, or extracts from, any record to which the condition in paragraph (d) relates, and
      - (ii) such other information,as may be so specified; 25
    - (f) *that there shall be paid to the Authority at such times as may be specified in directions sums of such amount as may be so specified in respect of its costs in connection with superintending compliance with the terms of licences.*
  - (5) Directions for the purposes of sub-paragraph (4) may be given in relation to licences generally, licences of a particular description or a particular licence. 30
- 3 (1) This paragraph applies to a licence authorising the storage of anatomical specimens.
- (2) It shall be a condition of a licence to which this paragraph applies that storage at the premises specified in the licence of the body of a deceased person for use for the purpose of anatomical examination shall not begin before that body's storage there for use for that purpose has been authorised in writing by – 35
  - (a) the designated individual, or
  - (b) an individual who has the Authority's permission to give such authorisation (see paragraph 12). 40
- (3) It shall be a condition of a licence to which this paragraph applies that any anatomical specimen which is stored at the premises specified in the licence shall be released from storage at the premises only into the possession of a person who is authorised in writing by the designated individual to have the specimen in his possession. 45
- (4) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give authority for the purposes of the condition in sub-paragraph (3) only if he is satisfied –



- (a) that the person to whom authority is given is a suitable person to have the specimen in his possession, and
  - (b) that that person intends to use the specimen only for the purpose of education, training or research.
- (5) It shall be a condition of a licence to which this paragraph applies that any authority given for the purposes of the condition in sub-paragraph (3) shall specify – 5
  - (a) the person to whom the authority is given,
  - (b) the specimen to which the authority relates,
  - (c) the purpose for which the specimen may be used, and 10
  - (d) the duration of the authority.
- (6) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give such notice of any authorisation for the purposes of the condition in sub-paragraph (3) as may be specified in directions. 15
- (7) It shall be a condition of a licence to which this paragraph applies that such information about authorisations for the purposes of the condition in sub-paragraph (3) as may be specified in directions shall be recorded in such form as may be so specified.
- 4 (1) This paragraph applies to a licence authorising the activity mentioned in section 13(2)(e). 20
- (2) It shall be a condition of a licence to which this paragraph applies that any former anatomical specimen which is stored at the premises specified in the licence shall be released from storage at the premises only into the possession of a person who is authorised in writing by the designated individual to have the specimen in his possession. 25
- (3) The condition in sub-paragraph (2) does not apply to the release from storage of a specimen for the purpose of its decent disposal.
- (4) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give authority for the purposes of the condition in sub-paragraph (2) only if he is satisfied – 30
  - (a) that the person to whom authority is given is a suitable person to have the specimen in his possession, and
  - (b) that that person intends to use the specimen only for the purpose of education, training or research. 35
- (5) It shall be a condition of a licence to which this paragraph applies that any authority given for the purposes of the condition in sub-paragraph (2) shall specify –
  - (a) the person to whom the authority is given,
  - (b) the specimen to which the authority relates, 40
  - (c) the purpose for which the specimen may be used, and
  - (d) the duration of the authority.
- (6) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give such notice of any authorisation for the purposes of the condition in sub-paragraph (2) as may be specified in directions. 45
- (7) It shall be a condition of a licence to which this paragraph applies that such information about authorisations for the purposes of the condition in sub-

paragraph (2) as may be specified in directions shall be recorded in such form as may be so specified.

*Power to impose conditions*

- 5        The Authority may grant a licence subject to such further conditions as it thinks fit. 5

*Pre-conditions to grant of licence*

- 6        (1) The Authority may not grant a licence in pursuance of an application unless the following requirements are met.
- (2) The proposed designated individual must—
- (a) be the applicant for the licence, or 10
- (b) consent to the application for the licence.
- (3) The Authority must be satisfied that the proposed designated individual—
- (a) is a suitable person to supervise the activity to be authorised by the licence, and
- (b) will perform the duty under section 15. 15
- (4) Where the applicant for the licence is not the proposed designated individual, the Authority must be satisfied that the applicant is a suitable person to be the holder of the licence.
- (5) The Authority must be satisfied that the premises in respect of which the licence is to be granted are suitable for the activity to be authorised by the licence. 20
- (6) A copy of the conditions to be imposed by the licence must have been shown to, and acknowledged in writing by—
- (a) the applicant for the licence, and
- (b) where different, the proposed designated individual. 25
- (7) In this paragraph, references to the proposed designated individual are to the individual whom the application proposes the licence designate as the person under whose supervision the activity to be authorised by the licence is to be carried on.

*Power to revoke licence*

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- 7        (1) The Authority may revoke a licence on application by—
- (a) the holder of the licence, or
- (b) the designated individual.
- (2) The Authority may revoke a licence otherwise than on an application under sub-paragraph (1) if— 35
- (a) it is satisfied that any information given for the purposes of the application for the licence was in any material respect false or misleading,
- (b) it is satisfied that the designated individual has failed to discharge, or is unable because of incapacity to discharge, the duty under section 15, 40
- (c) it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity,

- (d) it ceases to be satisfied that the person to whom the licence is granted is a suitable person to be the holder of the licence,
- (e) it ceases to be satisfied that the designated individual is a suitable person to supervise the licensed activity,
- (f) the designated individual dies, or
- (g) it is satisfied that there has been any other material change of circumstances since the licence was granted.

5

*Power to vary licence*

- 8 (1) The Authority may on application by the holder of a licence vary the licence so as to substitute another individual for the designated individual if— 10
- (a) the application is made with the consent of the other individual, and
  - (b) the authority is satisfied that the other individual is a suitable person to supervise the licensed activity.
- (2) The Authority may vary a licence on application by — 15
- (a) the holder of the licence, or
  - (b) the designated individual.
- (3) The Authority may vary a licence without an application under sub-paragraph (2) if it has power to revoke the licence under paragraph 7(2).
- (4) The powers under sub-paragraphs (2) and (3) do not extend to making the kind of variation mentioned in sub-paragraph (1). 20
- (5) The Authority may vary a licence without an application under sub-paragraph (2) by—
- (a) removing or varying a condition of the licence, or
  - (b) adding a condition to the licence.
- (6) The powers conferred by this paragraph do not extend to the conditions required by paragraphs 2(4), 3 and 4. 25

*Power to suspend licence*

- 9 (1) Where the Authority—
- (a) has reasonable grounds to suspect that there are grounds for revoking a licence, and
  - (b) is of the opinion that the licence should immediately be suspended,
- it may by notice suspend the licence for such period not exceeding three months as may be specified in the notice. 30
- (2) The Authority may continue suspension under sub-paragraph (1) by giving a further notice under that sub-paragraph. 35
- (3) Notice under sub-paragraph (1) shall be given to the designated individual or, where the designated individual has died or appears to the Authority to be unable because of incapacity to discharge the duty under section 15—
- (a) to the holder of the licence, or
  - (b) to some other person to whom the licence applies. 40
- (4) Subject to sub-paragraph (5), a licence shall be of no effect while a notice under sub-paragraph (1) is in force.
- (5) An application may be made under paragraph 7(1) or 8(1) or (2) notwithstanding the fact that a notice under sub-paragraph (1) is in force.



*Procedure in relation to licensing decisions*

- 10 (1) Before making a decision—
- (a) to refuse an application for the grant, revocation or variation of a licence, or
  - (b) to grant an application for a licence subject to a condition under paragraph 5,
- the Authority shall give the applicant notice of the proposed decision and of the reasons for it.
- (2) Before making a decision under paragraph 7(2) or 8(3) or (5), the Authority shall give notice of the proposed decision and of the reasons for it to—
- (a) the holder of the licence, and
  - (b) where different, the designated individual.
- (3) A person to whom notice under sub-paragraph (1) or (2) is given has the right to require the Authority to give him an opportunity to make representations of one of the following kinds about the proposed decision, namely—
- (a) oral representations by him, or a person acting on his behalf;
  - (b) written representations by him.
- (4) The right under sub-paragraph (3) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 28 days beginning with the day on which the notice under sub-paragraph (1) or (2) was given.
- (5) The Authority may by regulations make such additional provision about procedure in relation to the carrying-out of functions under this Schedule as it thinks fit.

*Notification of licensing decisions*

- 11 (1) In the case of a decision to grant a licence, the Authority shall give notice of the decision to—
- (a) the applicant, and
  - (b) the person who is to be the designated individual.
- (2) In the case of a decision to revoke a licence, the Authority shall give notice of the decision to—
- (a) the holder of the licence, and
  - (b) the designated individual.
- (3) In the case of a decision to vary a licence on an application under paragraph 8(1), the Authority shall give notice of the decision to—
- (a) the holder of the licence, and
  - (b) the person who is to be the designated individual.
- (4) In the case of any other decision to vary a licence, the Authority shall give notice of the decision to—
- (a) the holder of the licence, and
  - (b) the designated individual.
- (5) In the case of a decision to refuse an application for the grant, revocation or variation of a licence, the Authority shall give notice of the decision to the applicant.

- (6) Subject to sub-paragraph (7), a notice under sub-paragraph (2), (4) or (5) shall include a statement of the reasons for the decision.
- (7) In the case of a notice under sub-paragraph (2) or (4), the notice is not required to include a statement of the reasons for the decision if the decision is made on an application under paragraph 7(1) or 8(2).

5

*Permission for the purposes of the licence condition required by paragraph 3(2)*

- 12 (1) This paragraph applies to a licence authorising the storage of anatomical specimens.
- (2) The reference to the Authority's permission in the condition of the licence required by paragraph 3(2) ("the authorisation condition") is to –
  - (a) permission granted by the Authority on an application made, in conjunction with the application for the licence, by –
    - (i) the applicant for the licence, or
    - (ii) the person who, within the meaning of paragraph 6, is the proposed designated individual, or
  - (b) permission granted by the Authority on application by –
    - (i) the holder of the licence, or
    - (ii) the designated individual.
- (3) The Authority may grant permission to an individual for the purposes of the authorisation condition only if it is satisfied that the individual is a suitable person to give authorisation under that condition.
- (4) The Authority may revoke permission granted to an individual for the purposes of the authorisation condition –
  - (a) on application by the individual, the designated individual or the holder of the licence, or
  - (b) if it ceases to be satisfied that the individual is a suitable person to give authorisation under that condition.
- (5) Before refusing an application for the grant or revocation of permission, the Authority shall give the applicant notice of the proposed refusal and of the reasons for it.
- (6) Before revoking permission under sub-paragraph (4)(b), the Authority shall give notice of the proposed revocation and of the reasons for it –
  - (a) to the individual concerned, and
  - (b) to the designated individual and, where different, the holder of the licence.
- (7) Paragraph 10(3) and (4) shall apply in relation to notice under sub-paragraph (5) or (6) as to notice under paragraph 10(1).
- (8) In the case of a decision to refuse an application for the grant or revocation of permission, the Authority shall give notice of the decision to the applicant.
- (9) In the case of a decision to grant or revoke permission, the Authority shall give notice of the decision –
  - (a) to the individual concerned, and
  - (b) to the designated individual and, where different, the holder of the licence.

- (10) Notice under sub-paragraph (8), and notice under sub-paragraph (9) of revocation under sub-paragraph (4)(b), shall include a statement of the reasons for the refusal or revocation.
- (11) Where the Authority –
- (a) has reasonable grounds to suspect that there are grounds for revoking permission granted to an individual for the purposes of the authorisation condition, and 5
  - (b) is of the opinion that the permission should immediately be suspended,
- it may by notice suspend the permission for such period not exceeding three months as may be specified in the notice. 10
- (12) The Authority may continue suspension under sub-paragraph (11) by giving a further notice under that sub-paragraph.
- (13) Notice under sub-paragraph (11) shall be given to –
- (a) the individual concerned, and 15
  - (b) the designated individual and, where different, the holder of the licence.

*Applications under this Schedule*

- 13 (1) The Authority may by regulations make provision about applications under this Schedule and may, in particular, make provision about – 20
- (a) the form and content of such an application,
  - (b) the information to be supplied with such an application, and
  - (c) procedure in relation to the determination of such an application.
- (2) *An application under this Schedule shall be accompanied by such fee (if any) as the Authority may determine.* 25

SCHEDULE 4

Sections 32 and 34

INSPECTORATES: BOARDS

*Membership*

- 1 (1) The board of the Inspectorate shall consist of –
- (a) a chairman appointed by the Authority with the approval of the Secretary of State, 30
  - (b) the chief executive officer of the Inspectorate, and
  - (c) such number of other members appointed by the Authority as it thinks fit.
- (2) The Authority shall exercise its power to appoint members of the board of the Inspectorate to secure that at all times the membership of the board includes persons who have, and persons who do not have, a professional interest in any of the kinds of activity within the remit of the Inspectorate. 35



*Disqualification*

- 2 A person is disqualified for being appointed as chairman of the board of the Inspectorate if he is a member of the Authority.
- 3 (1) A person is disqualified for being appointed as chairman or other member of the board of the Inspectorate if – 5
- (a) he is the subject of a bankruptcy restrictions order or interim order,
  - (b) a bankruptcy order has been made against him by a court in Northern Ireland, his estate has been sequestrated by a court in Scotland or, under the law of Northern Ireland or Scotland, he has made a composition or arrangement with, or granted a trust deed for, his creditors, or 10
  - (c) in the last five years he has been convicted in the United Kingdom, the Channel Islands or the Isle of Man of an offence and has had a qualifying sentence passed on him.
- (2) Where a person is disqualified under sub-paragraph (1)(b) because a bankruptcy order has been made against him or his estate has been sequestrated, the disqualification shall cease – 15
- (a) on his obtaining a discharge, or
  - (b) if the bankruptcy order is annulled or the sequestration of his estate is recalled or reduced, on the date of that event. 20
- (3) Where a person is disqualified under sub-paragraph (1)(b) because of his having made a composition or arrangement with, or granted a trust deed for, his creditors, the disqualification shall cease –
- (a) at the end of the period of five years beginning with the date on which the terms of the deed of composition or arrangement or trust deed are fulfilled, or 25
  - (b) if, before then, he pays his debts in full, on the date on which the payment is completed.
- (4) For the purposes of sub-paragraph (1)(c), the date of conviction shall be taken to be the ordinary date on which the period allowed for making an appeal or application expires or, if an appeal or application is made, the date on which the appeal or application is finally disposed of or abandoned or fails by reason of its non-prosecution. 30
- (5) In sub-paragraph (1)(c), the reference to a qualifying sentence is to a sentence of imprisonment for a period of not less than three months (whether suspended or not) without the option of a fine. 35

*Tenure of office of appointed members*

- 4 Subject to the following provisions of this Schedule, the chairman and other appointed members of the board of the Inspectorate shall hold and vacate office in accordance with the terms of their respective appointments. 40
- 5 (1) The terms of appointment of the chairman and other appointed members of the board of the Inspectorate shall be such as the Authority may determine, subject to sub-paragraph (2).
- (2) Appointment as chairman or other member of the board of the Inspectorate shall be for a term not exceeding three years. 45

- |   |  |    |
|---|--|----|
| 6 | Previous service as chairman or other member of the board of the Inspectorate does not affect a person's eligibility for appointment to either office.                             |    |
| 7 | A person holding office as chairman or other appointed member of the board of the Inspectorate may resign that office by giving notice in writing to the Authority.                | 5  |
| 8 | A person holding office as chairman or other appointed member of the board of the Inspectorate shall cease to hold that office if he ceases to be qualified for appointment to it. |    |
| 9 | The Authority may remove a person from office as chairman or other appointed member of the board of the Inspectorate if it is satisfied that the person –                          | 10 |
|   | (a) has been absent from meetings of the board for six consecutive months, or longer, without the permission of the board, or  |    |
|   | (b) is unable or unfit to carry out his functions as chairman or other appointed member.   | 15 |

*Remuneration and pensions of appointed members*

- |    |   |    |
|----|---|----|
| 10 | (1) The Authority may pay to the chairman or any of the other appointed members of the board of the Inspectorate such remuneration as it may determine.   | 20 |
|    | (2) The Authority may pay, or make provision for paying to or in respect of, the chairman or any of the other appointed members of the board of the Inspectorate such pensions, allowances, fees, expenses or gratuities as it may determine.   |    |
|    | (3) The Authority may make a payment of such amount as it thinks fit to a person who ceases to hold office as chairman or other appointed member of the board of the Inspectorate otherwise than on the expiry of his term of office if it appears to the Authority that there are special circumstances which make it right for him to receive compensation. | 25 |

*Delegation* 30

- |    |  |    |
|----|--|----|
| 11 | The board of the Inspectorate may delegate any of their functions (to such extent as they may determine) – |    |
|    | (a) to any member of the board, or   |    |
|    | (b) to any member of the staff of the Authority who is assigned to assist the board of the Inspectorate.   | 35 |

*Proceedings*

- |    |   |    |
|----|---|----|
| 12 | The board of the Inspectorate may regulate their own procedure (including quorum).          |    |
| 13 | The validity of any proceedings of the board of the Inspectorate shall not be affected by – | 40 |
|    | (a) any vacancy in –  |    |
|    | (i) the office of chairman, or  |    |
|    | (ii) the post of chief executive officer,   |    |

- (b) any defect in a person's appointment as chairman or other member, or
- (c) the composition for the time being of the membership of the board.

*Staff, accommodation etc.*

- 14 The Authority shall provide the board of the Inspectorate with such staff, accommodation and other resources as the Authority thinks fit for the purpose of enabling the board to carry out their functions. 5

## SCHEDULE 5

Section 46

### SECTION 46: QUALIFYING CONSENT

#### PART 1 10

#### ENGLAND AND WALES AND NORTHERN IRELAND

##### *Introductory*

- 1 This Part of this Schedule makes provision for England and Wales and Northern Ireland about what constitutes qualifying consent for the purposes of section 46. 15

##### *Analysis for a scheduled purpose: DNA in relevant material from a human body*

- 2 (1) This paragraph applies where —
  - (a) the results of an analysis of DNA are to be used for a purpose which is specified in Schedule 1, and
  - (b) the DNA is in relevant material which has come from a human body. 20
- (2) The analysis shall be regarded as being the subject of qualifying consent if the use of the relevant material for the specified purpose is authorised under section 1(1) or (7).

##### *Analysis for a scheduled purpose: DNA not in relevant material from a human body*

- 3 (1) This paragraph applies where — 25
  - (a) the results of an analysis of DNA are to be used for a purpose which is specified in Schedule 1, and
  - (b) the DNA is in material which is not relevant material which has come from a human body.
- (2) In relation to analysis of DNA manufactured by the body of a person who is alive, "qualifying consent" means his consent, except where sub-paragraph (3) applies. 30
- (3) Where —
  - (a) the person is a child,
  - (b) neither a decision of his to consent, nor a decision of his not to consent, is in force, and 35
  - (c) either he is not competent to deal with the issue of consent or, though he is competent to deal with that issue, he fails to do so,



- “qualifying consent” means the consent of a person who has parental responsibility for him.
- (4) In relation to analysis of DNA manufactured by the body of a person who has died an adult, “qualifying consent” means –
- (a) if a decision of his to consent, or a decision of his not to consent, was in force immediately before he died, his consent; 5
  - (b) if paragraph (a) does not apply, the consent of a person who stood in a qualifying relationship to him immediately before he died.
- (5) In relation to analysis of DNA manufactured by the body of a person who has died a child, “qualifying consent” means – 10
- (a) if a decision of his to consent, or a decision of his not to consent, was in force immediately before he died, his consent;
  - (b) if paragraph (a) does not apply –
    - (i) the consent of a person who had parental responsibility for him immediately before he died, or 15
    - (ii) where no person had parental responsibility for him immediately before he died, the consent of a person who stood in a qualifying relationship to him at that time.

*Analysis not for a scheduled purpose*

- 4 (1) This paragraph applies where the results of an analysis of DNA are to be used otherwise than for a purpose specified in Schedule 1. 20
- (2) In relation to analysis of DNA manufactured by the body of a person who is alive, “qualifying consent” means his consent, except where sub-paragraph (3) applies.
- (3) Where – 25
- (a) the person is a child,
  - (b) neither a decision of his to consent, nor a decision of his not to consent, is in force, and
  - (c) either he is not competent to deal with the issue of consent or, though he is competent to deal with that issue, he fails to do so, 30
- “qualifying consent” means the consent of a person who has parental responsibility for him.
- (4) In relation to analysis of DNA manufactured by the body of a person who has died an adult, “qualifying consent” means his consent.
- (5) In relation to analysis of DNA manufactured by the body of a person who has died a child, “qualifying consent” means – 35
- (a) if a decision of his to consent, or a decision of his not to consent, was in force immediately before he died, his consent;
  - (b) if paragraph (a) does not apply, the consent of a person who had parental responsibility for him immediately before he died. 40

## PART 2

## SCOTLAND

*Introductory*

- 5 This Part of this Schedule makes provision for Scotland about what constitutes qualifying consent for the purposes of section 46. 5

*Analysis for a listed purpose*

- 6 (1) This paragraph applies where the results of an analysis of DNA are to be used for a listed purpose.
- (2) In relation to analysis of DNA manufactured by the body of a person who is alive, “qualifying consent” means his consent, except where sub-paragraph (3) applies. 10
- (3) Where—
- (a) the person is a child,
- (b) neither a decision of his to consent, nor a decision of his not to consent, is in force, and 15
- (c) either he is not competent to deal with the issue of consent or, though he is competent to deal with that issue, he fails to do so,
- “qualifying consent” means the consent of a person who has parental responsibilities in relation to him.
- (4) In relation to analysis of DNA manufactured by the body of a person who has died an adult, “qualifying consent” means— 20
- (a) if a decision of his to consent, or a decision of his not to consent, was in force immediately before he died, his consent;
- (b) if paragraph (a) does not apply, the consent of a person who stood in a qualifying relationship to him immediately before he died. 25
- (5) In relation to analysis of DNA manufactured by the body of a person who has died a child, “qualifying consent” means—
- (a) if a decision of his to consent, or a decision of his not to consent, was in force immediately before he died, his consent;
- (b) if paragraph (a) does not apply— 30
- (i) the consent of a person who had parental responsibilities in relation to him immediately before he died, or
- (ii) where no person had parental responsibilities in relation to him immediately before he died, the consent of a person who stood in a qualifying relationship to him at that time. 35

*Analysis not for a listed purpose*

- 7 (1) This paragraph applies where the results of an analysis of DNA are to be used otherwise than for a listed purpose.
- (2) In relation to analysis of DNA manufactured by the body of a person who is alive, “qualifying consent” means his consent, except where sub-paragraph (3) applies. 40
- (3) Where—
- (a) the person is a child,

- (b) neither a decision of his to consent, nor a decision of his not to consent, is in force, and
  - (c) either he is not competent to deal with the issue of consent or, though he is competent to deal with that issue, he fails to do so,
- “qualifying consent” means the consent of a person who has parental responsibilities in relation to him. 5
- (4) In relation to analysis of DNA manufactured by the body of a person who has died an adult, “qualifying consent” means his consent.
- (5) In relation to analysis of DNA manufactured by the body of a person who has died a child, “qualifying consent” means— 10
- (a) if a decision of his to consent, or a decision of his not to consent, was in force immediately before he died, his consent;
  - (b) if paragraph (a) does not apply, the consent of a person who had parental responsibilities in relation to him immediately before he died. 15

*Listed purposes*

- 8 (1) In this Part of this Schedule, references to a listed purpose are to a purpose in the following list—
- Anatomical examination;
  - Clinical audit; 20
  - Determining the cause of death;
  - Education or training relating to—
    - (a) human health, or
    - (b) research in connection with disorders, or the functioning, of the human body; 25
  - Establishing after a person’s death the efficacy of any drug or other treatment administered to him;
  - Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); 30
  - Public display;
  - Public health monitoring;
  - Quality assurance;
  - Research in connection with disorders, or the functioning, of the human body; 35
  - Transplantation.
- (2) In sub-paragraph (1), the reference to transplantation is to transplantation into a human body and includes transfusion.
- (3) The Secretary of State may by order amend this paragraph for the purpose of— 40
- (a) varying or omitting any of the purposes listed in sub-paragraph (1), or
  - (b) adding to the purposes listed in that sub-paragraph.



*Supplementary*

- 9 (1) Power to make orders under this Part of this Schedule is exercisable by statutory instrument.
- (2) Power to make orders under this Part of this Schedule includes power –
- (a) to make different provision for different cases, and 5
  - (b) to make incidental, supplementary, consequential or transitional provision or savings.
- (3) No order under this Part of this Schedule shall be made unless a draft of the statutory instrument containing it has been laid before and approved by a resolution of each House of Parliament. 10
- (4) Before acting under paragraph 8(3) or 10(4), the Secretary of State shall consult the Scottish Ministers.
- 10 (1) In this Part of this Schedule –
- “adult” means a person who has attained the age of 16 years;
  - “anatomical examination” means examination by dissection for purposes of teaching or studying, or researching into, morphology; 15
  - “child”, except in sub-paragraph (2), means a person who has not attained the age of 16 years;
  - “parental responsibilities” has the meaning given by section 1(3) of the Children (Scotland) Act 1995 (c. 36). 20
- (2) The following are qualifying relationships for the purposes of this Part of this Schedule, spouse, partner, parent, child, brother, sister, child of a brother or sister, stepfather, stepmother, half-brother, half-sister and friend of long standing.
- (3) For the purposes of sub-paragraph (2), a person is another’s partner if the two of them (whether of different sexes or the same sex) live as partners in an enduring family relationship. 25
- (4) The Secretary of State may by order amend sub-paragraph (2).

## SCHEDULE 6

Section 50

## POWERS OF INSPECTION, ENTRY, SEARCH AND SEIZURE 30

*Inspection of statutory records*

- 1 (1) A duly authorised person may require a person to produce for inspection any records which he is required to keep by, or by virtue of, this Act.
- (2) Where records which a person is so required to keep are stored in any electronic form, the power under sub-paragraph (1) includes power to require the records to be made available for inspection – 35
- (a) in a visible and legible form, or
  - (b) in a form from which they can readily be produced in a visible and legible form.
- (3) A duly authorised person may inspect and take copies of any records produced for inspection in pursuance of a requirement under this paragraph. 40

*Entry and inspection of licensed premises*

- 2 (1) A duly authorised person may at any reasonable time enter and inspect any premises in respect of which a licence is in force.
- (2) The power in sub-paragraph (1) is exercisable for purposes of the Authority’s functions in relation to licences.

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*Entry and search in connection with suspected offence*

- 3 (1) If a justice of the peace is satisfied on sworn information or, in Northern Ireland, on a complaint on oath that there are reasonable grounds for believing—
- (a) that an offence under Part 1 or 2 is being, or has been, committed on any premises, and
- (b) that any of the conditions in sub-paragraph (2) is met in relation to the premises,
- he may by signed warrant authorise a duly authorised person to enter the premises, if need be by force, and search them.
- (2) The conditions referred to are—
- (a) that entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant under this paragraph has been given to the occupier;
- (b) that the premises are unoccupied;
- (c) that the occupier is temporarily absent;
- (d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.
- (3) A warrant under this paragraph shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.

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*Execution of warrants*

- 4 (1) Entry and search under a warrant under paragraph 3 is unlawful if any of sub-paragraphs (2) to (4) and (6) is not complied with.
- (2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.
- (3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall—
- (a) produce the warrant to the occupier, and
- (b) give him—
- (i) a copy of the warrant, and
- (ii) an appropriate statement.
- (4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall—
- (a) produce the warrant to that other person,

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- (b) give him –
    - (i) a copy of the warrant, and
    - (ii) an appropriate statement, and
  - (c) leave a copy of the warrant in a prominent place on the premises.
- (5) In sub-paragraphs (3)(b)(ii) and (4)(b)(ii), the references to an appropriate statement are to a statement in writing containing such information relating to the powers of the person executing the warrant and the rights and obligations of the person to whom the statement is given as may be prescribed by regulations made by the Secretary of State. 5
- (6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises. 10
- (7) Where the premises in relation to which a warrant under paragraph 3 is executed are unoccupied or the occupier is temporarily absent, the person executing the warrant shall, when leaving the premises, leave them as effectively secured as he found them. 15

*Seizure in the course of inspection or search*

- 5 (1) A duly authorised person entering and inspecting premises under paragraph 2 may seize anything on the premises which he has reasonable grounds to believe may be required for purposes of the Authority's functions relating to the grant, revocation, variation or suspension of licences. 20
- (2) A duly authorised person entering and searching premises under a warrant under paragraph 3 may seize anything on the premises which he has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under Part 1 or 2. 25
- (3) Where a person has power under sub-paragraph (1) or (2) to seize anything, he may take such steps as appear to be necessary for preserving the thing or preventing interference with it.
- (4) The power under sub-paragraph (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized. 30
- (5) Where by virtue of sub-paragraph (1) or (2) a person seizes anything, he shall leave on the premises from which the thing was seized a statement giving particulars of what he has seized and stating that he has seized it. 35

*Powers: supplementary*

- 6 (1) Power under this Schedule to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.
- (2) Power under this Schedule to inspect or search any premises includes, in particular – 40
  - (a) power to inspect any equipment found on the premises,
  - (b) power to inspect and take copies of any records found on the premises, and
  - (c) in the case of premises in respect of which a licence is in force, power to observe the carrying-on on the premises of the licensed activity. 45



- (3) Any power under this Schedule to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person’s control as are necessary to enable the power of entry, inspection or search to be exercised.
- 7 (1) A person’s right to exercise a power under this Schedule is subject to his producing evidence of his entitlement to exercise it, if required. 5
- (2) As soon as reasonably practicable after having exercised a power under this Schedule to inspect or search premises, the duly authorised person shall –
- (a) prepare a written report of the inspection or search, and
- (b) if requested to do so by the appropriate person, give him a copy of the report. 10
- (3) In sub-paragraph (2), the “appropriate person” means –
- (a) in relation to premises in respect of which a licence is in force, the designated individual (as defined in section 43);
- (b) in relation to any other premises, the occupier. 15

### Enforcement

- 8 (1) A person commits an offence if –
- (a) he fails without reasonable excuse to comply with a requirement under paragraph 1(1) or 6(3), or
- (b) he intentionally obstructs the exercise of any right under this Schedule. 20
- (2) A person guilty of an offence under this paragraph is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

### Interpretation

- 9 In this Schedule, “duly authorised person”, in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision. 25

## SCHEDULE 7

Section 58

### CONSEQUENTIAL AMENDMENTS

#### *Wills Act 1837 (c. 26)* 30

- 1 In section 1 of the Wills Act 1837, in the definition of “will”, after “child,” there is inserted “and also to an appointment by will of a representative under section 4 of the Human Tissue Act 2004,”.

#### *Anatomy Act 1984 (c. 14)*

- 2 In section 4 (lawful examinations), in subsection (4) (which is expressed to be subject to subsections (5) to (8)), for “(5)” there is substituted “(6)”. 35

#### *Coroners Act 1988 (c. 13)*

- 3 (1) The Coroners Act 1988 is amended as follows.

- (2) In section 19 (post-mortem examination without inquest), after subsection (1) (which confers power to direct a person to make a post-mortem examination) there is inserted –

(1A) No direction under subsection (1) above shall have effect to require a person to make a post-mortem examination if the making of the examination by him would contravene section 13(1) of the Human Tissue Act 2004 (under which a person may make a post-mortem examination only under the authority of a licence under that Act)."

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- (3) In section 21 (which confers powers to direct a person to make a post-mortem examination in connection with an inquest), after subsection (4) there is inserted –

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“(4A) No direction under this section shall have effect to require a person to make a post-mortem examination if the making of the examination by him would contravene section 13(1) of the Human Tissue Act 2004 (under which a person may make a post-mortem examination only under the authority of a licence under that Act).”

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*Human Organ Transplants Act 1989 (c. 31)*

- 4 In section 1(1)(a) of the Human Organ Transplants Act 1989, for “Great Britain” there is substituted “Scotland”.

*Criminal Justice and Police Act 2001 (c. 16)*

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- 5 (1) Part 2 of the Criminal Justice and Police Act 2001 (powers of seizure) is amended as follows.

- (2) In section 57 (retention of seized items), in subsection (1) (provisions in relation to which the section has effect), at the end there is inserted –

“(q) paragraph 5(4) of Schedule 6 to the Human Tissue Act 2004.”

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- (3) In section 66 (interpretation of Part 2), in subsection (4) (references to a search to include references to activities authorised by virtue of specified powers), at the end there is inserted –

“(n) paragraph 2 of Schedule 6 to the Human Tissue Act 2004 (entry and inspection of licensed premises).”

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- (4) In Schedule 1 (powers of seizure), in Part 1 (powers to which section 50 of the Act applies), after paragraph 73D there is inserted –

“Human Tissue Act 2004 (c. 00)

73E Each of the powers of seizure conferred by the provisions of paragraph 5(1) (seizure of material relevant to licensing functions) and (2) (seizure of evidence of offences) of Schedule 6 to the Human Tissue Act 2004.”

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*Enterprise Act 2002 (c. 40)*

- 6 (1) The following provisions –

- (a) paragraph 3(1)(b), (2) and (3) of Schedule 2, and  
(b) paragraph 3(1)(b), (2) and (3) of Schedule 4,

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shall be taken to be within the definition of “provision” in section 268 of the Enterprise Act 2002 (c. 40) (power to remove bankruptcy disqualifications under pre-8th November 2002 provisions or extend them to, or replace them with disqualifications of, persons subject to bankruptcy restrictions regimes).

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(2) In its application by virtue of sub-paragraph (1), section 268 of the Enterprise Act 2002 shall have effect with the following modifications—

(a) subsections (5)(d), (6) to (8) and (15) (power to make application of disqualification provision subject to person’s discretion) are omitted, and

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(b) for subsection (13) (order under section to be made by statutory instrument after parliamentary approval of a draft) there is substituted—

“(13) An order under this section—

(a) must be made by statutory instrument, and

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(b) shall be subject to annulment in pursuance of a resolution of either House of Parliament.”

## SCHEDULE 8

Section 59

### REPEALS AND REVOCATIONS

#### PART 1

20

#### REPEALS

<i>Short title and chapter</i>	<i>Extent of repeal</i>	
Human Tissue Act 1961 (c. 54)	The whole Act.	
Human Tissue Act (Northern Ireland) 1962 (c. 19 (N.I.))	The whole Act.	25
Anatomy Act 1984 (c. 14)	The whole Act.	
Corneal Tissue Act 1986 (c. 18)	The whole Act.	
Human Organ Transplants Act 1989 (c. 31)	The whole Act.	
National Health Service and Community Care Act 1990 (c. 19)	In Schedule 9, paragraph 7.	30
Human Fertilisation and Embryology Act 1990 (c. 37)	In Schedule 4, paragraphs 8 and 9.	
Health Authorities Act 1995 (c. 17)	In Schedule 1, paragraph 92.	35



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PART 2

REVOCATIONS

<i>Title</i>	<i>Extent of revocation</i>	
Corneal Tissue (Northern Ireland) Order 1988 (S.I. 1988/1844 (N.I. 14))	The whole Order.	5
Human Organ Transplants (Northern Ireland) Order 1989 (S.I. 1989/2408 (N.I. 21))	The whole Order.	
Health and Personal Social Services (Northern Ireland) Order 1991 (S.I. 1991/194 (N.I. 1))	In Part II of Schedule 5, the entry relating to the Human Tissue Act (Northern Ireland) 1962.	10
Anatomy (Northern Ireland) Order 1992 (S.I. 1992/1718 (N.I. 11))	The whole Order	15

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# Human Tissue Bill

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A

## B I L L

To make provision with respect to activities involving human tissue; to make provision about the transfer of human remains from certain museum collections; and for connected purposes.

*Presented by Mr Secretary Reid  
supported by  
The Prime Minister, Mr Secretary Blunkett,  
Mr Secretary Murphy, Secretary Tessa Jowell,  
Mr Paul Boateng, Mr Peter Hain  
and Ms Rosie Winterton.*

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*Ordered, by the House of Commons,  
to be Printed, 3rd December 2003.*

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